CARBON FIBRE AS A PROSTHETIC MATERIAL

IN

ORTHOPAEDICS

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Contents

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1.2.

Some material recorded in this thesis has already been published. A list of publications relating to the author's work on carbon fibre is included at the end of the thesis.

This thesis has been composed entirely by the author. The great majority of the work outlined is entirely the work of the author. Assistance was given in the examination of some histological sections and their interpretation, and in the strength testing of some specimens of tendon referred to in the text.

Note on Histological Preparations

All operations and all specimens were carried out and prepared by the author. Sections were cut under the supervision of the author by Mr Gareth Watkins of the Department of Orthopaedics, University Hospital of Wales. Advice on the staining was given by Dr Z A Ralis and Professor B McKibbin of theDepartment of Orthopaedics, University Hospital of Wales. All photographs were taken by the author with some assistance from the Department of Medical Photography, University Hospital of Wales.

ABSTRACT OF THESIS

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Title of Thesis " CARBON FIBRE AS A PROSTHETIC MATERIAL IN ORTHOPAEDICS "

The place for carbon fibre as a prosthetic material in orthopaedics is examined.

The early development of implant materials and the problems associated with their use, both from the point of view of material strength and biological inertness is examined. A brief description of the historical milestones in implant surgery is described.

A review of currently acceptable materials which are used in surgical practice is presented. The potential advantages of carbon fibre as a prosthetic material are outlined and the development of this material in recent years is described.

A series of experiments on rats, chickens, rabbits and sheep are described in which both the rigid and flexible forms of carbon fibre are examined. Initial experiments on rigid carbon fibre suggested that this material exhibited a higher degree of biological inertness than other conventional implant materials.
Experiments described demonstrate this to be the case but later attempts to use the material in clinical practice have proved disappointing. This is largely because the mechanical disadvantages outweigh the biological advantages of the material in this form.

In the examination of filamentous carbon fibre, it has been shown that advantage can be gained from both its biological and mechanical properties. First in animals and later in humans, it has been possible to demonstrate the actual induction of new tendons and ligaments in response to the presence of filamentous carbon fibre. Experimental evidence is presented to support the statement that true tendon induction does in fact occur, and a small number of clinical cases are described to demonstrate the practical use of this material.

In summary, this thesis describes the development of a hitherto unused material in orthopaedic practice and concludes with the suggestion that the material has a real and necessary place in the management of certain conditions in the human.

Use other side if necessary.

CARBON FIBRE AS A PROSTHETIC MATERIAL IN ORTHOPAEDICS

Introduction

An implant, in order to be perfect, must not only mimic the behaviour of the structure it is replacing, but also behave biologically in an exactly similar manner to normal tissue. It must therefore do no more than promote the mildest temporary inflammatory reaction associated with the trauma of the operation, and must be totally accepted within the body. If an implant can be developed which not only has all the properties outlined, but which, having acted as a replacement, gradually disappears from the site of implantation leaving only newly formed tissue, similar in all respects to that found in an otherwise normal situation, then that implant would truely be ideal.

This thesis advances the suggestion that carbon, which can now be manufactured in various forms, may be used in certain selected situations in a manner in which it does in fact, behave as the ideal implant material.

EARLY IMPLANT HISTORY

Implants vary in nature in a manner similar to biological tissue and similarly they are divided into rigid and flexible. While no biological tissue is truely rigid, no implants are truely rigid either, although, in the case of metallic and other hard materials, the inability to deform and differences in elasticity, may lead to either implant or supporting tissue failure.

To simplify definitions, rigid implants include metals, some plastics, glass, ceramic, epoxy, epoxy-reinforced carbons, and carbon reinforced carbons.

Flexible implants include cloths, rubber, sylastic and glues, and flexible carbon tow.

The rigid implants are largely used to replace or support body tissue of a so-called rigid nature, i.e. bone, or to encase other materials where contact with normal biological tissue would produce an adverse reaction, as in pacemaker batteries. Other applications are in replacement of moving parts such as heart valves where the mechanical advantages of the hard implant, outweigh the disadvantages of the possible flexible implant.

The flexible implants replace or support soft pliable biological tissue where the mechanical property of pliability or deformation is the prime concern. Examples include materials used in hernia repair, sutures, tendon and vessel replacement.

It is not the intention of this thesis to present an exhaustive description of all implants and implant materials. However, it is felt that a brief resume of the various major implant materials and their properties is appropriate in view of the arguments which are advanced in favour of carbon in its rigid or flexible forms.

The majority of early work on implants was in the field of Orthopaedics since bone, the most rigid of body tissues, lends itself to various methods of internal fixation and replacement. Prior to the days of antiseptic technique, there was little chance of any advance, since any surgical technique suffered the triple hazard of the operation itself, the implant used, and associated infection. However, early in the 19th century, well before the Listerian period, Levert (1829) had already demonstrated that implant failure might be due to factors other than infection or operative technique. In his now classical experiments, he demonstrated that the noble metals caused less tissue reaction than others, and laid the foundations for work which continues today into tissue irritability and reaction to the presence of implants. Further progress, however, was not made for nearly a century, until others examined not only the material of an implant and its behaviour in living tissue, but also the relative strengths and mechanical suitability of various materials. It was perhaps inevitable that metals should have been thought of as the more suitable implant materials, particularly since the interest was primarily in orthopaedic procedures.

Hansman (1866) demonstrated that fractures could be held with plates and that healing would occur, but no thought was given to the acceptance or otherwise of his nickel plated steel plates. Lane (1893, 1914) also used steel plates and showed their value in internal fixation. Sherman (1912) while having the same interests as Lane, considered the mechanical details of his fixation devices, and it is no small tribute to him that his designs of forearm plates are still widely in use today.

While Sherman's care in the design of his plates, and his fortunate choice of Vanadium steel has led to wide acceptance of his views, the same cannot be said for others who disregarded the merits of comparatively inert materials and used the less acceptable phosper-bronze or aluminium plates. (Cotton 1912).

Early interest in the choice of metal rather than the design, was demonstrated by Lambotte (1913).

Gradually the concept of suitability of design, and an acceptable choice of implant material led to rational use of various materials in varying situations. Clearly where no great stress was involved, a soft, yet inert material was the correct choice and Cushing's (Cushing 1911) original clips are still in use today. However, where rigidity was required, vanadium steel was the material of choice (Venables and Stuck 1947).

While interest continued in the types of metal available for implants, the development of different alloys continued (Pudenz 1943, Venables and Stuck, 1947, Leventhal 1951, Peyton and Hall, 1941).

By the early part of the twentieth century, it had become apparent that there was more to implant design than tissue support, and that while adequate strength of the supporting implant was important, so too was tissue acceptability of the implant material.

It is not surprising, perhaps, that orthopaedic surgeons, having developed the basic techniques of internal fixation, using metals, have largely favoured continual use of metals in this field. Other materials such as ivory (Hey-Groves 1926) were tried, both in peg fixation and in early joint ~~fixation~~ replacement. The mechanical advantages of metal malleability, strength, and ease of manufacture have, until recently, meant that the majority of rigid implants have been metallic, while the basic design problems are largely the province of the engineer.

The basic biological problems are those of tissue acceptability and hence the province of the physician and surgeon.

The ideal metallic implant is one in which the elasticity of the metal conforms to the body tissue and in supporting or replacing procedures, no tissue reaction to the implant is seen.

Corrosion has been recognised as a two-fold problem; it represents the deterioration of the implant material and reflects an adverse response of the tissue environment to the implant. Speed (1935), Harris (1938), and Raagaard (1939), recognised this in their attempts to develop corrosion resistant stainless steel. Early lack of appreciation of the different perameters involved is well demonstrated by the history of the Judet prosthesis (Scales and Zarek 1954). The underestimation of the mechanical forces in the hip joint led to the early fracture of the Judet stems. Failure to evaluate the wear properties of polymethylmethacrylate led to excessive wear of the articular surface. The basic design and use of two dissimilar materials and their method of attachment to each other led to corrosion of the steel and crazing of the acrylic.

Rigid implant design today is based on the correction of errors of the past, but surprisingly, the only metals currently in use are stainless steel, vitallium, tantalum ,titanium and cobalt chromium and of these, the first three have been in constant use since the 1930's.

While the range of metallic implant materials remains limited, virtually by comparatively early exclusion of all but a few alloys, the range of other materials for use in all fields, especially those other than orthopaedics, is expanding.

Of the earlier non-metallic implants the most rapid early advances came in the post-war period using plastics and other polymer based materials.

REVIEW OF RECENT (POST-WAR) IMPLANT MATERIALS

METALS

Alloys and Pure Metals

Scales (1953), Calnan (1963) Williams (1971) have all tried to define the requirements of an implant, and in many respects, metals meet many of these requirements.

They lend themselves to the easy production of the required implant shape.

The mechanical and physical properties are usually suitable for function.

Compatibility in most modern implant alloys with surrounding tissues is significantly good and causes comparatively little early problems. Metals in use today are relatively non-toxic and can be manufactured in sufficient strength to fulfil their designed role.

However, they are not ideal implant materials. While there are problems in the manufacture of implants using either cast or wrought cobalt chromium alloys, namely work hardening during manufacture (the work hardening rate is so high that casting is the only feasible practice in manufacture), the main advantages are those of low corrosion and low evidence of metal-tissue reaction.

Corrosion is the destruction of metallic structure by the action of the surrounding medium. Whether the corrosion is due to the metal medium interface reaction, or metal oxide medium interface, depends on the nature of the metal. While the main corrosive problem in all implants is electro-chemical in nature, surface irregularities, PH alteration, and bacterial corrosion are all significant.

An advantage of chromium is the early formation of the oxide which provides surface film formation and hence corrosion protection. This feature is shared by other alloys and many pure metals, for example, titanium rapidly forms titanium oxide, but in alloy form, titanium has shown even greater corrosion resistance (Hoar and Mears 1966).

Electro-chemical corrosion depends on the development of an electro-potential between metal and solution. If a metal is placed in an electrolyte (i.e. a solution of dissolved salts producing a positive and a negatively charged ion) there will be a transfer of ions from solution to solid and visa-versa. The ion transfer is greater from metal to solution than solution to metal, with the resultant development of a negative potential. As more positive ions pass into solution, the potential difference increases and at an equilibrium state the measured potential is steady, and is the electro-potential. Different metals and different electrolytes will produce different electro-potentials, but in surgical practice, the only electrolyte that matters is saline. The electro-chemical series which is readily established, indicates corrosive behaviour. Since increased electro-chemical potential represents greater ionic movement there is therefore a greater tendency to corrosion in that solution.

Cobalt is fairly active as a pure metal (electro-potential of -0.28 volts using 0.0. hydrogen electrode at 25°C compared with gold +1.45) but in an alloy its activity falls. It is actually more realistic to measure the activity of a metal in an electrolyte when the surface activity or positivity has been stabilised. Hence, titanium, represented electro-chemically, is mis-leadingly active (electro-potential -1.63 compared with gold, +1.45) but when presented in the galvanic series in saline, it lies fourth behind platinum, gold and silver, and truely represents its low corrosive behaviour. While the development of an oxide, as in the case of titanium, can be an advantage in protection against corrosion, the same oxide formation can be a disadvantage as a corrosion cell may be formed :- rusting is just such a process, and has precluded the use of iron as a basic implant material.

Coupled with the disadvantage to the implant itself of corrosion, there is the much greater problem of the effect of particulate corrosion products or solutes released from the implant, and its effects on local and distant tissues. While there is no doubt that cobalt products are found in surrounding muscle and fibrous tissue, (Ferguson, Laing and Hodge 1960), titanium particles and iron particles from stainless steel (Meachim 1972) are also found, it is generally felt that disadvantageous though these findings may be, they are not of sufficient severity to preclude the use of the metals involved.

However, there is no doubt that the surrounding tissues do react to the presence of foreign metallic fragments by the production of an inflammatory cell response, and mature to a dense fibrosis. Tantalum (Burch and Carney 1938, Pudenz 1943, Robertson 1944,)used in the wire form produces similar histological appearances. Zerconium (Bechtol, Ferguson and Laing 1958, Bates, Reiners and Horn, 1958) while differing slightly from titanium in its physical make-up, differs little in tissue reaction. Silver (Venables and Stuck 1947) while low in the corrosion scale, produces a marked inflammatory response (Pudenz 1948).

The double problems of tissue-metal biological response and metal corrosion have recently led to the rigid applications of the British (British Standards Institute 1968) and American (American Soceity for Testing of Materials 1965 and 1967) standards in manufacture of all commonly used alloys and stainless steels. Despite careful manufacture, it is not possible to make a metal implant which, while answering physical requirements, does not corrode, and which does not produce a tissue reaction. In the absence of corrosion, the absence of tissue response and the absence of infection, anyone of the three commonly used metals, stainless steel, titanium, and chrome cobalt alloy, would be ideal. Infection is a problem in all implants, even autogenous bone grafting, but the other two major disadvantages await to be overcome in the development of totally inert metals, or metal substitutes, which will offer the advantages and none of the disadvantages of the metals they may replace.

CURRENT ALTERNATIVES TO METALLIC IMPLANTS

Rigid Implants

GLASS

Smith Peterson (1939) having observed that glass provoked the formation of a pseudo-capsule but apparently little other reaction, was prompted to use glass as a weight bearing surface in joint replacement. His examination of this problem was encouraged by the suggestion that new joint regeneration could perhaps be promoted and certainly the pseudo-capsule which formed over the glass appeared to lend encouragement to the idea. However, glass proved to lack mechanical strength and the early collapse of glass implants, rendered the material unsuitable.

There are three main types of deformation of any rigid material:

a. Time-dependent, plastic deformation beyond the elastic limit (which is partly dependent on time).

b. Fracturing at the limit of elastic deformation

c. The brittle fracture which occurs in glass is of the third type and is due to the fact that it is easier for a crack to nucleate and propagate, than for dislocation to be generated, and thus produce plastic deformation. Brittle solids such as glass are weak because they contain structural features which act as stress concentrations. Crack nucleation thus occurs because there is no crack averting mechanism.

FIBREGLASS

Fibre-glass is prepared in such a way that plastic deformation is possible, thus overcoming, to some extent, the brittle features of glass. The drawing and flame-polishing with the growth of whiskers by vapour deposition, thus offers new physical features to the basic material. However, the main improvement in plastic deformation of fibre-glass over glass is in the resin coating applied to fibre-glass, which allows further deformation, and which enables micro cracks to appear without initial significant loss in strength. However, there has been no significant development of fibre-glass for use in implant surgery to day.

CERAMICS

Ceramics are substances which have ionic bonds joining atoms of metallic and non-metallic elements. Most orthopaedically useful ceramics contain two or more types of ion, such as the silicates. The atomic arrangement of silicone enables an ionic bond to be formed with positive metal ions, such as zinc, or aluminium. The harder ceramics have the characteristic appearance of porcelain or china whereas alternative structural arrangements exist where ceramic can be made porous. An example of such a substance in use in surgical practice is the dental implant material "Synthos". While porous and biodegradable porous ceramics (Hulbert, Young, Matthews, Klawitter, Talbert and Stelling, 1970) have not yet earnt a place in clinical implant surgery, the brittle ceramics, despite their problems in manufacture, have, largely because of their excellent wear properties been of use in joint replacement surgery. While the merit of low wearing properties is clearly seen in joint surface replacements, the inherent tendency to fracture has been the major reason for present general low usage of ceramics in implants. The brittleness is due to the ionic arrangement which actively inhibits plastic deformation (dislocation) and results in fracture rather than alteration in shape.

However, leaving aside the brittle nature of ceramics, there are alternative properties in implantation in addition to the low-wear properties already referred to. Early work on ceramic implants by Smith (1963) drew little favour, largely because ceramics used were not ceramics at all; rather they were ceramic resin composites and the foreign body reaction now thought to be due to the resin, appeared to offer more disadvantages than advantages.

Hulbert, Young, Matthews, Klawitter, Talbert and Stelling (1970) examined the possible use of porous ceramics, looking this time, not at the wear or strength properties, but at the ability of tissue to grow into different sized pores in ceramic implants using calcium alluminate implants with pore sizes ranging from 10 microns - 20 microns. They observed in the femora of dogs, initial ingrowth of connective tissue and later, in the larger pores, initiation of centres of calcification of osteoid type lamella bone within the pores. There was no adverse inflammatory response and it was suggested that a chemical reaction between bone and calcium alluminate was responsible for the apparent bone induction (Klawitter and Hulbert 1972). Further evidence of the chemical induction of bone was offered by Heintrich, Graves, Stein and Bajpei (1971) who showed that whilst ceramics based on aluminum and zerconium had excellent compatibility with bone, only those containing calcium stimulated new bone growth. Others have also confirmed this feature of porous ceramic implants (Rhinelander, Roumeyhe, and Milner, 1971).

POLYMERS

Carbon can combine with hydrogen and other atoms to form large molecules, the polymers. Carbon is unique in this respect with the exception of silicone which can also form high molecular weight polymers. The majority of polymers in use in the implant field are based on carbon. By varying the momomers both by nature and by number, a vast variety of polymers can be produced.

Since they are an important group of implants and since in relation to carbon composites some have particular relavence to this thesis, they will be discussed briefly, but individually.

ACRYLIC

Strictly speaking, the name acrylic is applied to a polymeric material containing at least 85% polyacrylonitrile, but it is more commonly used to denote polymethylmethacrylate. This material has gained wide use in orthopaedics, primarily as a bone cement, and is largely discussed in this context.

Its use is not limited to orthopaedics although its initial application was an implant manufacture (Judet, Judet, L'Estrange and Dunoyer 1954). Excessive faith in mechanical strength of polymethylmethacrylate led to early mechanical disintegration (Scales and Zarek 1954, Scales 1967). Bone replacement, where high strength is not required has offered a use for acyrilic. Healey, Sudbay, Mebal, Hoffmann and Duval (1954) have performed one stage mandibular resections with acrylic replacement. Cranioplasty and nasal augmentation (Gonzallez - Ulloa and Stevens (1964), ear reconstruction (Wilde and Tur 1964), and urinary incontinence procedures (Berry 1961, Berry 1965) have been successfully performed with acrylic.

It is, however, as a bone cement that it has found its greatest implant usage.

Charnley's definition (Charnley 1970) of a cement as a substance which acts solely as a mechanical bond between surface irregularities on the different parts and which requires considerable bulk between the surfaces which are not accurately coapted, distinguishes cement from adhesives. Polymethylmethacrylate has no adhesive properties and is a true cement, and like all acrylic plastics, it is strong and brittle. The tensile strength, tensile modulus, and flexural strength are high and the tendency to creep low, but the suseptability to stress solvent crazing means that if high mechanical loading is required of the cement, the simple way to overcome this disadvantage is to increase bulk. It is thus fortuitous that in the cementing of Charnley's prosthesis, for example, a considerable bulk of cement is commonly used. Clearly, a cement which exhibits high strength characteristics but which exhibits excessive tissue response is of little use.

The usual foreign body response is the accumulation of polymorpho-nuclear leucoytes followed by macrophage invasion. Foreign body giant cells develop and surround the implant, themselves being surrounded by a dense fibrous reaction. The polymorph and macrophage response is not limited to implantation of foreign bodies but the presence of giant cells certainly indicates the presence of foreign material. Thus the absence of a foreign body giant cell response tends to indicate that a material is inert. Calnan (1963) suggests that the response of living tissue to an implant which does not show a giant cell reaction is highly favourable, since the later development of the fibrous capsule virtually renders the implant material extra corporeal. However, Charnley (1970) suggests that the presence of giant cells is not a true indication of significant irritation. Methylmethacrylate has been shown to excite such a response without apparent disadvantage, even many years after implantation. Charnley regards the cellular response of tissue to methylmethacrylate as no more than an inflammatory cell response and that this is itself a precursor to a healing process. Of perhaps greater importance is the size and shape of the implanted material, whether it be solid, particulate, fibrous, or in another form. Large particles or blocks of methylmethacrylate excite little or no reaction (Stone and Herbert 1953, Henrickson, Jansen, and Krough-Poulson 1953, Wiltse, Hall and Stenehjem 1957), but small particles of the same material always evoke the florid giant cell reaction (Stinson 1965).

The clear concise and detailed description by Charnley (1970) has meant that methylmethacrylate has come to be regarded as the best cement available for implant fixation. While it is certainly true that there is a foreign body giant cell response to the non-particulate cement, there is no accumulation of such cells; in fact, their number decreases with time.

POLYHYDROXYETHYLMETHACRYLATE

When dry, polyhydroxyethylmethacrylate resembles polymethylmethacrylate, but when hydrated, becomes sponge-like. Early uses as breast augmentation implants (Kliment, Stod, Fahoun and Stokar 1968) failed, because not only did the sponge become encapsulated with fibrous tissue, but woven bone also rapidly formed (Winter and Simpson 1969).

EPOXY RESINS

Usually the higher the molecular weight of a polymer, the greater the degree of water insolubility and the lower the toxicity. Epoxy resins are low molecular weight polymers but the toxicity is inversely proportional in their case to the molecular weight (Le Faux 1968). Their main industrial use as glues suggested to some that they might be used as surgical adhesives in clinical practice. However, the rate of bond formation in room temperature of the epoxy resins is too slow for practical clinical application (Cooper and Falb 1968).

Their main place in implant surgery is in encapsulation of the power source of cardiac pacemakers, primarily, because they can provide satisfactory mechanical support, but also because they serve as a barrier to moisture and provide electrical insulation (Debney 1971). They also have the possible advantage of increasing clotting time (Leninger, Falb and Grobe, 1968.)

CELLULOSIC MATERIALS

An implant, which is designed to maintain its former strength over a long period of time, must clearly be made of a material which is not only comparatively inert, but one which is not altered or digested by body fluids. However, an implant which is required to only provide temporary support such as a suture material, should ideally provoke little reaction, but be readily digested after a certain time. Insoluble cellulose is readily converted to soluble sugar by cellulase enzymes of cellulolitic micro-organisms. However, this feature is sufficiently unreliable to preclude the use of cellulosic materials in this situation. Soluble regenerated cellulose is thrombogenic by its physical nature in the form of a sponge, but other cellulosic materials may have a place in the preparation of antithrombogenic surfaces. Regenerated cellulose has been evaluated for haemostatic purposes by Lebendiger, Gitlitz, Hurwitt, Lord and Henderson (1960) and its use described by Skoog (1967).

POLYETHYLENE

Ingraham, Alexander, and Matson (1947) initially used polyethylene sponge and reported a high degree of tissue acceptability. Others (Grindlay and Waugh 1951, Neuman 1957) reported similar favourable results, but in 1963, Calnan and later Stinson (1965) showed less enthusiasm when they were able to show an excessive fibrous reaction with a massive giant cell response, and cautioned others from using the low density polyethylene sponge. While low molecular weight polythene is too soft for use in load bearing and wear situations, polyethylene detritous resulting from wear, excites a similar fibrous and foreign body reaction. High density polyethylene is well tolerated. Charnley, Kamangar, and Longfield (1969) using high density ultra high molecular weight polythene showed that wear resistance was high and that the particles resulting from wear were small and produced a lower degree of tissue reaction. Other uses of polythene include shunts, in the treatment of hydrocephalus (Nulsen and Spitz 1951). The use of polythene tubes has been superceded by silicone rubber (Rickham and Johnston 1960). Polythene tubing in ureteral replacement (Kaufman 1967) has been superceded by Teflon (Ulm and Kraus 1960). Polythene blocks are in use as tempero-mandibular joint spacers (Gordon 1958) and this plastic is still widely used in plastic and reconstructive surgery (Wilde and Tur 1964).

POLYETHYLENE TETRATHALATE

In the assessment of tissue reaction to any implant, not only the chemical nature but the physical characteristics must be examined. Multi-filamentous materials generally induce a greater response than mono-filaments, and yet this very ability to induce a mild fibrous reaction can be of value. Polyethylenetetrathalate woven as a cloth (Dacron) certainly encourages the infiltration of fibrous tissue in its interstices and when used as a vessel patch, or replacement, has the additional valuable property in the case of low thrombogenicity (De Bakey, Jordan, and Beall 1965, Braunwald and Bull 1969). Its major disadvantage is that the ingrowth of fibrous tissue is in no way controlled and may in time actively occlude the vessel itself.

Other uses include orbital floor reinforcements in severe fractures, fixation for springs in eyelids in facial palsy, fixation of silicone rubber in urethral patching (Sankey and Heller, 1967) and other uses where an alternative material needs to be held to underlying soft tissue. (Masson, Payne, and Gonzalez 1970).

POLYUROTHANE

Polyurothanes demonstrate the typical aclaim and subsequent disillusionments so frequently associated with all new implant materials. Indeed, it is possible that carbon (see below) may in time come to show the same implant history, although the evidence so far suggests that the degree of cautious optimism, later expressed in this thesis, may be reasonable.

Mandorino and Salvatore (1959) showed to their satisfaction that the comparatively rigid polyurothane foam they studied, was non-toxic and osteogenic, while others (Redler 1962, Thompson and Sezgin 1962) agreed that it might have a place as a space filler, they disagreed on the two fundamental stated advantages, of Mandorino and Salvatore, that it was not truely osteogenic. Thompson and Sezgin, and Redler doubted the non-toxic aspects of the claim. Redler demonstrated an extensive fibrous reaction to the implanted foam. Charnley (1970) suggests that the chemical presence and thermal damage of the polymerisation process precludes its general use. However, modification of the nature of the actual polyurothane (as a polyether) resulted in little reaction to implantation in this form, and it is this type of polyurothane which is now stimulating interest (Boretos, Detner and Donachy 1971).

POLYPROPYLENE

Similar in structure to polyethylene, polypropylene has better physical properties in terms of elastic modulus, tensile strength and flexural strength, and has a longer fatigue life. It is therefore especially suitable as an internal hinge (Calnan and Reis 1968).

POLYMIDES (NYLONS)

Nylon has fallen into disrepute because of excessive tissue reaction, rapid degradability, and (probably the main reason), confusion over the great variability of different types of nylons. Degradability is due in part to the hydrophylic nature of nylons and the resultant loss of tensile strength with water absorbtion (Scales 1957). Harrison and Adler (1956) showed that 83% of tensile strength of woven nylon of unspecified type, was lost after a 174 days implantation, and suggested that this loss of strength was due to chemical degredation. Scales (1957) demonstrated that there was a marked tissue reaction to the polymer but following degredation to the monomer, the monomer itself did not induce such a profound reaction. He concluded that while chemical degredation was responsible for its weakening, it was the physical effect of particulate material and not the chemical nature of the implant which was responsible for the marked tissue reaction. Because of the unreliable nature of degredation, the use of nylon where permanent form and fixation was required, has rather tended to preclude its regular use. Today, the only regular use of polyamides in implant surgery is in suture materials. Here, nylon, is wrongly regarded as a non-absorbable suture material with the implication that it maintains its form and strength. From the preceeding remarks, it can be seen that this is not so; rather, it is relatively non-absorbable and hence relatively non-degradable, but it has achieved its permanent status on the basis of slow degredation to a point where new tissue has formed which has then taken over the holding function of the nylon suture by the time any significant degredation occurs .

POLYTETRAFLUROETHYLENE (PTFE)

Polytetraflurœthylene is probably the most inert material currently in use as an implant (Williams and Roaf 1973). It does not degrade or absorb water. In Calnan's study (1963) it was shown not to be truely inert, but in comparison with other materials, there was shown to be less round cell infiltration and while giant cells were seen in association with PTFE felt, no such giant cells were seen in association with solid or sheet PTFE. The implication is that the giant cell reaction is a feature of the physical (i.e. the felt) make-up, rather than the chemical nature of the material.

The presence of a giant cell reaction to the PTFE felt would suggest that there would be a similar response to particulate PTFE. PTFE wears and produces particulate detritus as a result of such wearing (for example in the Charnley hip prosthesis) (Charnley, Kamangar, and Longield 1969, Leidholt, and Gorman 1965), and the particulate matter induces both acute, and later chronic, inflammation with histiocytes and giant cells in adjacent soft tissue. Despite this, the almost negligible response to solid PTFE has led to its widespread adoption as a suitable weight-bearing material in joint prostheses. One interesting use of the tissue response of the particulate detritus is to induce fibrosis of a purposeful nature in the reconstruction of vocal chords (Lewy 1966)

PHENOLFORMALDEHYDE

There is no place in implant surgery for this material, but it is included, partly for historical reasons as one of the earliest polymers which were considered, but mainly because it demonstrates a major problem following implantation of some substances and one which must be considered before any material is considered for surgical use.

Tumour formation defined as an abnormal mass of tissue, the growth of which exceeds and is uncoordinated with that of normal tissue and persists in the same excessive manner after cessation of stimuli which have evolved the change (Willis 1967), has been shown to follow implantation of phenolformaldehyde. Turner (1941) showed tumour formation in 50% of rats following implantation. This observation has naturally led to suspicion of all implants, and as shown later, has actively excluded some materials. It has also stimulated interest, not only in the chemical, but also in the physical form of the implant (Oppenheimer, Oppenheimer, Stout, Eirich, 1955).

POLYVINYL ALCOHOL

Woven materials have already been mentioned. Polyvinyl alcohol has largely historical importance since it was amongst the first of the cloth prostheses to be examined (Voorhees, Jaretski and Blackmore 1952). Here the reaction between the implant and body tissue, rather than being considered as an undesireable feature, was a positive advantage. Blood flowing through the intesteses of the cloth, rapidly clotted and subsequent organisation of fibrin and growth of new fibrous tissue resulted in a water-proof lasting graft in vascular repair. It has now been superceded by polyhydroxyethylmethacrylate (see above), and like this polymer has the unfortunate property of encouraging calcification as well as fibrosis (Dukes and Mitchley 1962).

POLYACETYL

Polyacetyl is the polymer of formaldehyde and because of its resistance to creep fatigue and abrasion, has been extensively used in heart valve prosthesis such as the Bjork-Shirley valve. The major disadvantage is the difficulty in autoclaving in that not only is there a tendency for heat degredation to formaldehyde to occur, but polyacetyl absorbs water during auto-claving and therefore rapidy distorts.

POLYACRYLONITRILE

My main interest in this material stems from its use as a basic polymer from which carbon fibre is prepared. This aspect is discussed below. It does, however, have uses in its commercial form (Orlon) and has been compared favourably with polyethylene tetrathalate (Dacron) and polytetrafluroethlene (Teflon). When used in its woven form, its behaviour is not disimilar from Dacron and Teflon, except that of these three, Teflon behaves less variably and suffers less loss of tensile strength following prolonged implantation (Harrison 1959). It is used extensively as a suture material. However, because it is well tolerated and non-absorbable (Postlethwaite, Schaube, Dillon and Morgan 1959), it is readily manufactured as a co-polymer with vinyl chloride (Vinyon N) and vinylacetate (Acrylan) and these polmers have similar uses as the parent material.

SILICONES

Silicones are polymers based on silicone rather than carbon atoms. Depending on the length of the polymer chain, polydimethyl siloxane can exist as a fluid (low molecular weight) or a rubber like material of varying rigidity (high molecular weight). Whether used as a fluid or a semi-solid, it exhibits similar properties, in that implantation of silicone results in little more than a healing reaction which is similar to that seen in a sterile wound (Mullison 1966). When silicone implants were placed in abdominal subcutaneous tissue, peritoneal cavity or cerebral cortex in rats, all implants were invested with a connective tissue capsule (Agnew, Todd, Richmond and Chromsier 1962). While there is no reaction to the implantation of fluid at the implantation site other than capsular formation (the thickness of which is directly proportional to the length of time following implantation), the silicone fluid is phagocytosed and can be found throughout the rèticulo-endothelial system (Hawthorne, Ballantyne, Rees, and Seidman 1970). The excellent lubricating properties of silicone fluid have been explored in joint lubrication, but there has been no long term advantage in this. However, silicone fluid does have a very definite place in implantation, primarily as a space filler. While there is a disadvantage in its partial dispersal and formation of microcysts, there is no evidence to suggest that there are any toxic effects following cyst formation or dispersal (Rees, Ballantyne and Hawthorne 1970). The development of soft tissue prostheses such as the breast prosthesis now in widespread use has led to a combination of different types of silicone in which a semi-solid silicone bag is filled with a silicone gel and tissue fixation is encouraged by a backing of Dacron weave for chest wall fixation (Cronin and Greenberg 1970).

Semi-solid silicone rubber appears to have only two disadvantages as an ideal implant. The first is ready deformation, and the second is poor tear strength. However, the soft rubbery nature can be turned to advantage and this, coupled with its almost inert behaviour, temperature stability, resistance to chemical and enzymatic degradability, offer many advantages. It has been used as a valve material in hyrocephalus (Rickham 1964) cystostomy prostheses (Weinberg and Pagovitch 1969), finger joints (Swanson 1972) tendon reconstruction (Carrol and Bassett 1963) heart valve balls (Lee, Zaragoza, Callaghan, Couves, and Sterns 1970), although here deformation has proved a problem as in many places in plastic and reconstructive surgery.

The use of silicones as a synovial fluid alternative have met with limited and a short term success (Eguro 1972, Helal 1968).

NATURAL RUBBER

Natural rubber is a polymer of isoprene and is usually modified by vulcanisation (addition of sulphur). It has the advantages and possible uses of silicone rubber but has been largely replaced in implant surgery by the latter, because of the severe adverse tissue reactions associated with natural rubber.

GLUES

With the exception of cyanoacrylates other substances available as surgical adhesives have already been referred to.

a. Cyanoacrylates - The major advantage of cyanoacrylates is one of rapid polymerisation and hence rapid setting, together with their ability to produce breaking strength in skin wounds similar to suturing (Sussman, Milch, Blair, Person and Yeager 1966). Their main use in surgery is in ophthalmic surgery (Refojo 1971). Unlike the majority of other implants, the cyanoacrylates are totally biodegradable and are replaced by tissue in the healing process. Usually, biodegradability is regarded as a disadvantage, but in this case, it is clearly a positive advantage. The breakdown products do not appear to be particularly noxious and are excreted by the kidney, in urine, liver in faeces, and via the lungs.

b. Natural Rubber Adhesives - These require a solvent which either evaporates or is absorbed. The problems in their use are therefore compounded by their own low tissue acceptability and reaction to the solvent. In addition, the bonds are weak and setting time is too long for practical use.

c. Epoxy Resins - The rate of setting is too slow for practical use. (Cooper and Falb 1968).

OTHER BIODEGRADABLE MATERIALS

Mention has been made of the biodegradable characteristics of a number of polymers with adverse effects mitigating against their use in the majority of cases. However, it is clear that in some cases, such as the cyanoacrylates, this can be a positive advantage. The concept of a material which has a surgical application and is satisfactory in this application in that it is absorbed or in some other way disappears from the site of implantation leaving healthy tissue behind, is obviously attractive. Tissue glues are one such example. The other major place for such materials is in sutures.

SUTURE MATERIALS

Non absorbable materials include a number of polymers already referred to (most of which tend to lose tensile strength within several months) and more traditional materials such as silk, cotton, and wire. All multi-filament materials produce a greater tissue reaction than mono-filamentous sutures and the traditional materials produce more reaction than synthetics (Dettinger and Bowers 1957). The absorbable sutures have traditionally been made of cat-gut which produces an intense inflammatory reaction with polymorphonucleocytes, lymphocytes, plasma cells and frequently micro-abcesses (Echeverria and Jiminez 1970) but recently synthetic absorbable sutures have been introduced.

Polyglycolic acid has a number of advantages over catgut (Katz and Turner 1970). It maintains its tensile strength for a greater period of time. Its biodegradability pattern is reproducable and it produces little more than a slight acute-on-chronic inflammatory reaction with fibrous tissue and lymphocyte infiltration.

<u>CARBON FIBRE</u>

Carbon arises in many forms as clearly seen by its appearance in nature, in such widely differing forms as graphite and diamond. The biological application of carbon however, lies in the polymeric carbons, that is polymers of carbon in which the carbon-carbon bond is arranged in such a way that a solid material results.

All polymers contain carbon atoms. When polymers of high molecular weight are heated in an inert atmosphere above $300^{\circ}C$, they lose much of their non-carbon content as gases,leaving mainly carbon behind. This is carbonisation. The slower process where liquids or tars are formed results in an impure carbon, known as coke. However, if they can be induced to bypass this intermediate (coke) stage, Char results. Only when temperatures in excess of $1000^{\circ}C$ are recorded are all non-carbon factions driven off, leaving pure carbon, but below 1000°C the materials are known as Pyropolymers and above that, Polymeric Carbon.

Charcoal is the char of cellulose. Cellulose is a polymer of relatively high molecular weight and it, together with lignin, is the main component of wood. When polymerised by heat, the redundant char is not only impure but even when heated above 1000°C it has no mechanical strength.

The polymeric carbon of cellulose does maintain its original shape and was first used by Edison as filaments in electric lights. Graphatisation is the term reserved for so called soft carbons which soften on heating to higher temperatures in the region of 2,700°C. Non-graphatisable carbons are those which do not soften at this temperature and are therefore known as hard. Such carbons are the glassy carbons developed by Davidson and Losty (1963).

In 1961, Shindo produced polymeric carbon of good strength and stiffness from polyacrylonitrile and it is from this material that our source of carbon derives. (Shindo 1963).

The carbon-carbon bond is the basic arrangement of any polymeric carbon and the arrangement of the outer electrons when the carbon atom is bonded to its neighbours is the determining factor in the latter form of carbon fibre or other carbon. For example, in the tetrahedral state, the surrounding four atoms are arranged in such a way that they form a tetrahedron with the carbon nucleus at the centre. Bonded in a three dimensional form, they result in a carbon lattice and form the hard crystaline solid, diamond. When in the trigonal state, the fourth electron is free and can form other bonds as in ethylene (CH2=CH2).

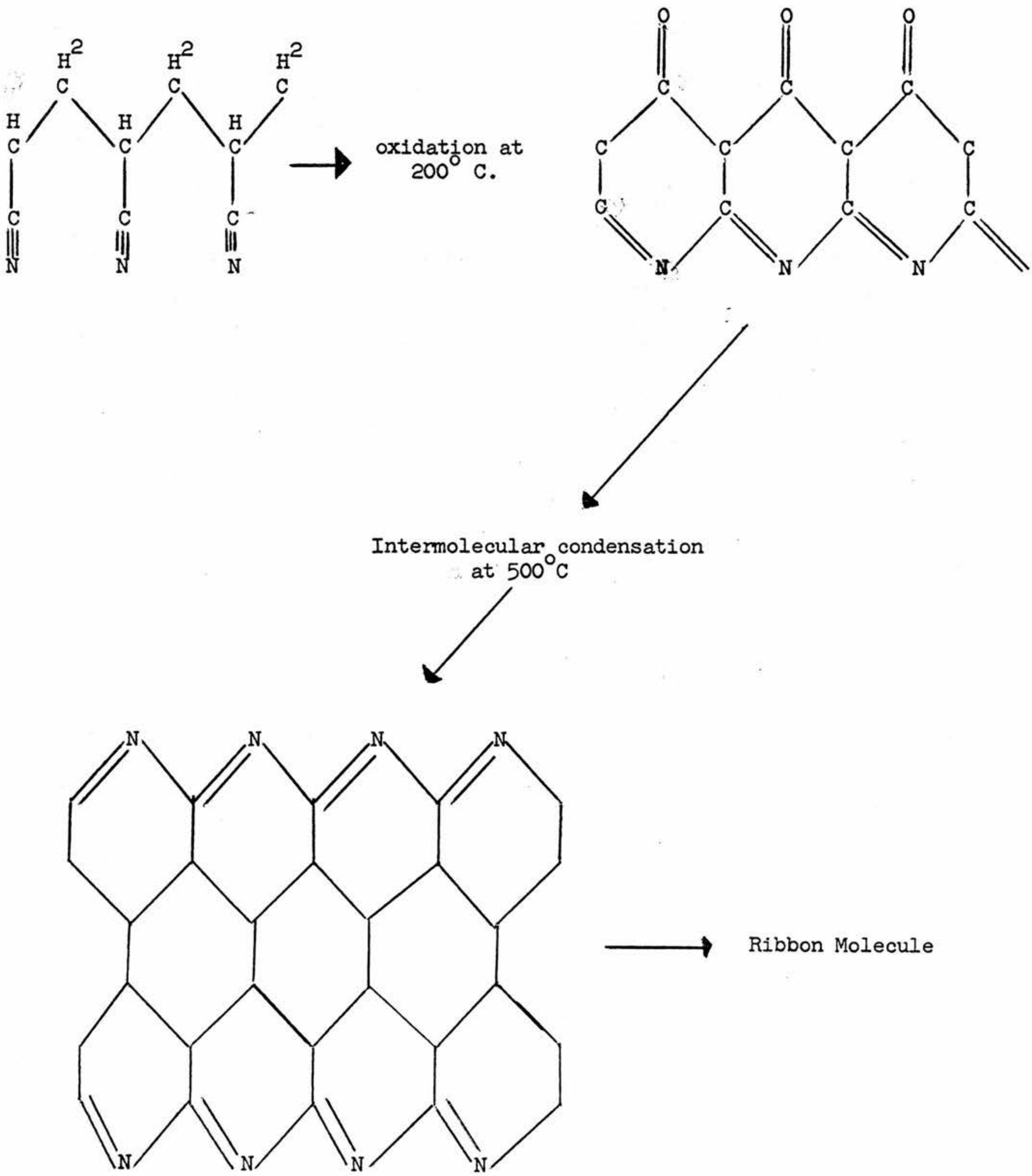
Graphitic materials all exist in this state in which parallel sheets of carbon atoms are arranged. Polymeric carbons exist in this state but are arranged to form long entwined graphite ribbons. In the digonal state, there are two electrons which are arranged either side of the nucleus and the remaining pair are free as in the gas, acetylene (CH), (Jenkins and Kawamura 1976).

The polymeric carbons (of the trigonal state) depend for their inherent strength on their ability to lie parallel to each other and on the nature of the groupings attached to the chains. Not all polymeric carbons have intrinsic strength. Carbonised polymers such as polystyrene lack symetry and it is thus impossible for the chains to pack closely together. They therefore exist as polymeric glasses, but others such as polythene with a symetrical arrangement of hydrocarbon atoms polymerise easily, leaving a material of great strength and stiffness in two directions lacking only strength in the third dimension, that being governed by weak intermollecular cohesion. The natural orientation of the chain is referred to as the preferred orientation and it is a feature of such materials that a high degree of preferred orientation, that is the high degree of orderly relationship one to another, results in high tensile modulus and strength. When polymers are heated in an inert atmosphere (pyrolised) the chains may remain intact and will merely coalesce with neighbouring chains. Early in the heating process, there is rapid weight loss in which oxygen, chlorine and nitrogen and other atoms are removed and later at temperatures above 1,200°C, hydrogen is gradually eliminated. An example of weight loss is that of polyacyrylonitrile in which there is a loss of 66% loss of weight (Madorsky 1964). The resultant fibre for many polymer precursors depends on the nature of the precursor, and in the case of polyacyrylonitrile, it is the ability for the polymer to oxidise in an orderly manner to another polymer then to condense above 500°C to a carbon ribbon molecule which makes it particularly attractive as a precursor in the formation of carbon fibre.

Japanese workers (Shindo 1963) experimented with carbon fibre production initially from molten pyrolysis products of polyurethane chloride and coal tar pitch and were able to demonstrate that it is not essential to start carbon fibre production from polymeric starting materials. Polyvinylchloride pitch softens in nitrogen gas at temperatures above 150°C and forms a liquid above 200°C. The pitch can then be extruded into fibres which will maintain their shape during later carbonisation. These fibres show no preferred orientation and have little strength. Other pitches such as petroleum coal tar are now made commercially as carbon fibres, but the greater strength exhibited by these fibres is achieved by oxidation with ozone, thus increasing the intermollecular cross links. Yamada (1968) first succeeded in making glassy carbon filaments from a complex phenolic resin. Phenolic resins have low molecular weights and prior to 1967 no-one had achieved Yamada's success. He found that in resins with a molecular weight in excess of 10,000 filaments formed and soft resins could be spun under pressure, and within a nitrogen atmosphere. By altering the pressure and temperature together with an increase of curing time, fibres of large length and small diameter (less than 20 microns) could easily be drawn. The actual carbonisation is a very complicated process which is carefully controlled to avoid individual fibre adhesion.

High modulus fibres are produced by alignment of the C-C bonds, parallel to the fibre axis. Graphite whiskers of no importance

PREPARATION OF CARBON FIBRE



Incipient Carbon Ribbon Molecule

in surgical implants to date have perfect alignment and a Youngs modulus of 1,000 GN/M^{-2} (the highest in nature). Stretching produces preferred orientation in many polymeric systems but only polyacyrylonitrile maintains this orientation after stretching (Shindo 1963).

DEVELOPMENT OF THE MANUFACTURING PROCESS OF CARBON FIBRE

The first serious attempt to make high strength carbon fibres was at the Wright-Patterson Airforce Base at Ohio. Here they developed the difficult technique of stretching viscose rayon up to 50% at temperatures in the vicinity of 2,000°C to give a carbon fibre with improved mechanical properties. This process was developed commercially by the Union Carbide Company, (British Patent No. 1.179-324). Thornel 25 was placed on the market at a price in excess of £1,000 per klg. In this process a highly oriented cellulose fibre was carbonised to give a carbon fibre with a comparitively low modulus of 70 GN/M^{-2} and this fibre was subsequently stretched at 2,500°C to give a high modulus fibre. This was followed by the introduction of fibres such as Thornel 40 and Thornel 50. The work of Shindo of the Industrial Research Institute at Osaka has already been referred to. He was the first to make carbon fibres from polyacyrilonitrile and he showed that it was possible to make high mechanical strength carbon fibres from pyrolising polyacrylonitrile yarn. He failed, however, to exploit the commercial potential of these findings and merely patented the process used. Independently, Johnson and Watt (1967) started work on the production of carbon fibre from polyacrylonitrile precursors and it was not until their work was well underway that they learnt of Shindo's contribution. "Courtelle", a polymer of polyacrylonitrile fibre made by Courtaulds (UK) which had a high theoretical melting point and underwent little chain scission during heat treatment was particularly promising and Courtaulds subsequently developed a special acrylic fibre for conversion to carbon fibre. The workers at the Royal Aircraft Establishment applied for a patent in 1964 covering their process as stated by Johnson and Watt (1967). This was a technique of improving fibre orientation by restraining the natural shrinkage of the fibre during the initial carbonisation at quite a low temperature without recourse to stretching at high temperature. Rolls-Royce had been working independently of the Royal Aircraft Establishment and had developed a process with a very long carbonisation cycle and were able to successfully adopt the Royal Aircraft Establishment process.

In the Royal Aircraft Establishment process, three stages were used for the conversion of Polyacrylonitrile precursor into carbon fibres:

1. Oxidisation at 200-300°C
2. Carbonisation in an inert atmosphere at about 1,000°C
3. Graphitisation in an inert atmosphere at temperatures in excess of 2,000°C.

The precursor is pyrolysed driving off all elements other than carbon without seriously disrupting the configuration of the carbon fibre backbone chain. A first requirement for the precursor is that when heated it should not melt before decomposition; a condition satisfied by polyacrylonitrile. The highly polar cyanide group causes strong dipole-dipole forces to operate between molecules inhibiting molecular motion with resultant high melting temperatures.

The first stage in the process is one of oxidisation and the fibres are heated in air at about 220°C when disorientation and shrinkage occur unless the fibres are constrained. Johnson and co-workers did this by winding the precursor onto a rigid frame which prevented shrinkage and eliminated the need for constraint to be applied at a later stage during carbonisation. The oxidised fibre, now black, is cut from the frames and carbonised by heating for many hours at 1,000 - 1,500°C in an inert atmosphere to drive off elements other than carbon. The volotiles evolved include ammonia, hydrogen, cyanide and water (Watt 1972).

A number of other British workers were eminent in this early work on carbon fibre. In the spring of 1966 the Atomic Energy Research Establishment at Harwell, were invited by the Royal Aircraft Establishment to use their existing equipment and expertise to develop techniques for the production of carbon fibres on a large scale for use by the Ministry of Technology.

Following normal practice, exploitation of the Royal Aircraft Establishment patent was handled by the National Research Development Corporation. British companies who were licenced to develop carbon fibres commercially, included Rolls-Royce, Courtaulds Limited and Morganite Research and Development Ltd.,

Since the Royal Aircraft Establishment patent (British Patent 1,148,874) was filed, the industrial companies involved in carbon fibre manufacture have carried out their own research and development work so that each has developed its own process which is not disimilar to the processes described in the original patents. Each company has filed its own patent applications. In 1971 production of carbon fibres to the Royal Aircraft Establishment patent was commenced in the United States by the Whittaker Corporation and by the Morgan Crucible and Hercules Company, by arrangement with Courtaulds.

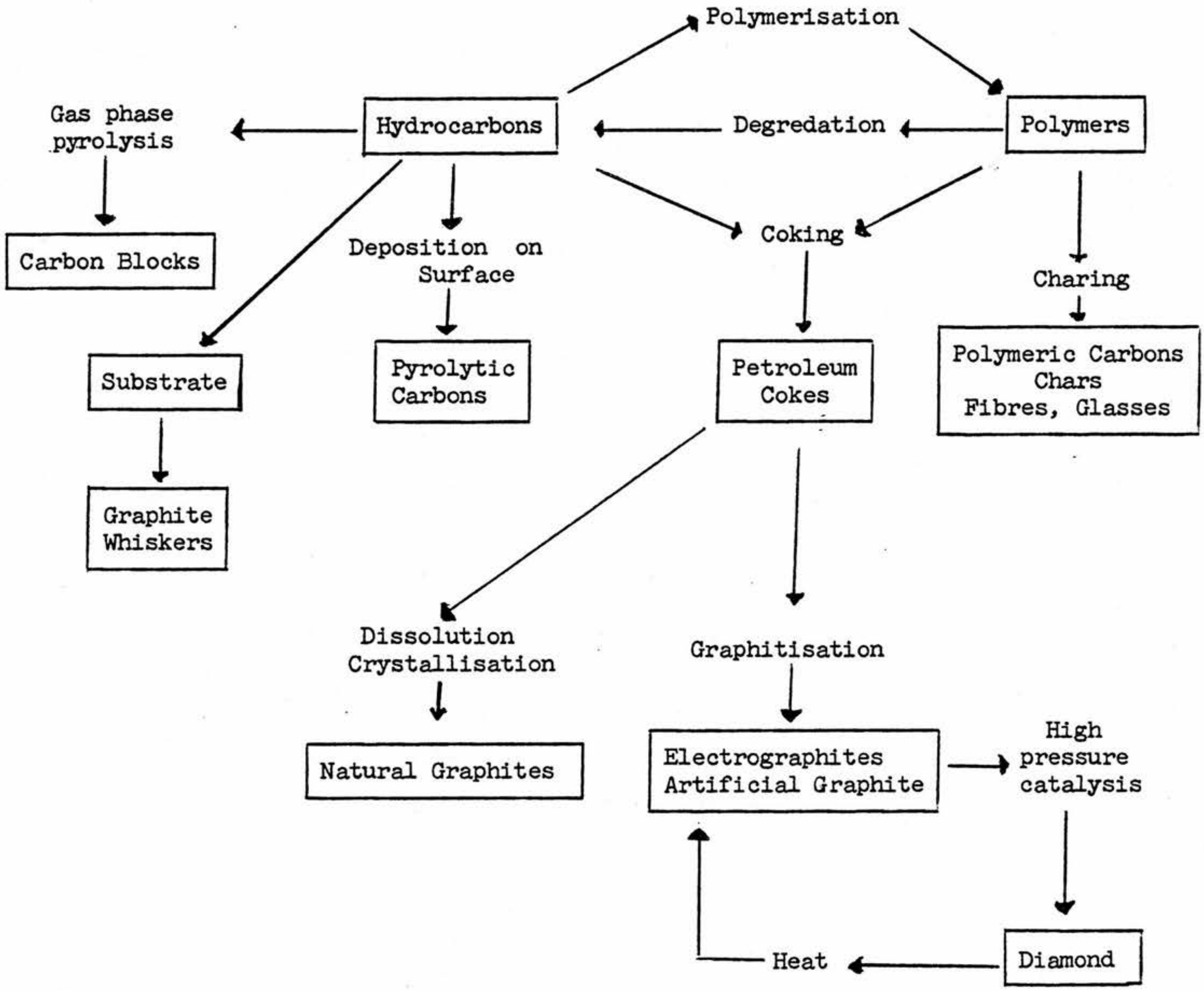
Many firms have since turned their attention to carbon fibres made from the polyacrylonitrile precursor, and includes companies in the United Kingdom, United States, Japan, West Germany and France. Carbon fibres with improved mechanical properties have been obtained by relaxation of polyacrylonitrile precursor in water and by hot stretching the polyacrylonitrile precursor in glycerol at 130-160°C. Variations on the various methods adopted in preparation have included the addition of a volatile alkyl borate which has been found to catalyse the graphitisation process (Celanese Corporation, United States patent 3656904 1972).

Neutron irradiation of carbon fibre with and without boron doping has been shown to significantly increase the strength and modulus (Allen, Cooper and Mayer 1969).

Although most of the work on the production of high performance carbon fibres has used polyacrylonitrile as the precursor material, alternative materials have been studied.

For example, cellulose fibre used as the precursor material with gaseous hydrogen chloride can be made to increase the yield of carbon fibre by assisting the elimination of water,and Nippon Carbon Co. hold the patent on this process (United States patent 3529934:1967). Pitch can similarly be used as a precursor material for the production of carbon fibres. The pitch is refined followed by melt spinning, taking care that the individual filaments are kept apart whilst they harden. Crude asphalt can also be refined and a pitch fibre melt spun to give a graphite fibre by stretch graphitisation with a microstructure similar to polyacyrilonitrile and highly oriented viscose rayon (Hawthorne, Baker, Bentall and Linger 1970).

VARIOUS FORMS OF CARBON



Unless an alternative is found to hot stretching these fibres at graphitisation temperatures of up to 2,700°C, it is at the moment uneconomic to use such processes commercially.

Chemistry of Carbon Fibre Formation

The early work of Standage and Matkowsky (1969) on the pyrolysis of polyacrylonitrile up to 400°C suggested that during oxidation of unsaturated hydrogen bonding, hydroxyl groups and carbonyl groups were introduced. The nitrile groups participate in a secondary polymerisation reaction causing cyclization. It is suggested that the reason for polyacrylonitrile based fibres being so successful at producing high performance carbon fibres is the possibility of initially creating a highly oriented molecular structure with the ability to introduce thermal stability without serious degradation and molecular disorder. This means that the essential features of fibre structure are retained during carbonisation. The oxidised fibre can be considered as a stiff planar cyclized ring connected by relatively mobile linear segments (Clarke and Bailey 1973). The oxidation reaction is intramolecular and an increase in oxidation time gives a resultant increase in formation of ladder polymer, the slower heat giving stronger fibres. It has been shown that intermolecular linking in oxidised polyacrylonitrile does not start until 300-400°C. The pyrolysis takes place in two stages. Firstly, there is a decomposition of unladdered parts of the polyacrylonitrile polymer with some end to end linking of the laddered parts. The second stage from 500-1000°C involves intermolecular reactions with the evolution of hydrogen cyanide and nitrogen leading to the development of an oriented structure. Discrete flaws within and on the surface of the polyacrylonitrile control the tensile strength of the pyrolysed fibre. This has led to efforts to produce so called 'clean' polyacrylonitrile (Morton and Watt 1974).

Structure of Carbon Fibres

A wide range of techniques have been employed to study the nature of carbon fibres including high resolution electron microscopy and X-rays (Ergun 1972), high energy photo-electron spectroscopy (Barber Swift, Evans and Thomas 1970). It has been shown by high resolution microscopy that in a high modulus polyacrylonytrile based carbon fibre there are three distinct structural phases : A well orientated highly crystalline graphite phase, a less well orientated crystalline phase and a small proportion of the three dimensional graphite phase.

Fabrication Techniques

The four main ways of fabricating composition carbon fibre and resin are wet lay up, the use of preimpregnated carbon fibre web, filament winding and injection moulding. The wet lay up process is a method primarily used for control work in a laboratory and entails taking the requisite amount of carbon fibre,wetting out thoroughly with a resin which may be heated to reduce the viscosity to aid penetration, placing in one half of the mould and inserting a plunger, which can be a close fit with open ends to enable the surplus resin to drain away when the mould is closed. Or the mould can be a closed type with a loose fit plunger with just sufficient clearance to permit the flow of excess resin, but not large enough to allow the fibre to extrude.

After closing the mould, it is heated to cure the resin. The wet lay up process is generally used for fabrications using carbon/glass hybrid tapes and braids.

Preimpregnated carbon fibre web is normally supplied as carbon fibre warp in a range of thicknesses. The requisite number of preimpregnated plies is taken and cured either in a compression mould in a press, or an autoclave using a vacuum bag technique (Molyneux 1973). The first part of the cure cycle is to advance the resin viscosity to prevent excessive flow when pressure is applied followed by gelation and final cure.

In the filament winding processes, the fibre can be wound spatially along a rotating cylindrical mandrel or wound end over end along the major axis of a rotating mandrel with rounded ends. Winding can be carried out using a wet impregnation process bypassing the fibre through a bath of resin or using carbon fibre tow preimpregnated with resin. The number of filaments in a carbon fibre tow controls the width the tow can be uniformly spread and affects the minimum diameter an item can be wound. A smaller tow thus permits smaller winding diameters. Below this minimum diameter, the fibre would tend to buckle and not fully transmit the applied load (Hardwick 1975).

Cost of Carbon Fibres

The Select Committee on Science and Technology (HMSO 1969) considered that at that time it was of the utmost national importance that a large scale plant for producing carbon fibre should be built in the United Kingdom without delay and estimated that the 1968 price of £220/kg (UK) would reduce this cost to £11 per kg. or less. In 1977 the continuous fibre is offered for sale at a price between £60 and £100 per kg. depending on fibre type. For large quantities the price falls considerably and in the type of carbon fibre examined in this thesis, a price as low as £18 per kilogramme has been achieved Since comparatively small quantities are required for biological work at this stage, the fall in price is reflected by the increased industrial use of this material.

SUMMARY OF THE USES FOR CARBON FIBRE OTHER THAN THE POTENTIAL BIOLOGICAL USES OUTLINED BELOW

Carbon fibre on its own has little value in industry but when combined with other materials in the form of carbon fibre composites, the advantages of light weight and great strength lend it to many uses. Carbon fibre has been incorporated in many matrices and probably the metal matrices have posed the most problems. (Howlet 1971). The major use of such composites is in the Aerospace Industry but it is of interest that approximately 500,000 golf clubs, 2,500 fishing rods and 50,000 tennis rackets are made annually from carbon reinforced plastics. Other items include hockey sticks, ski poles, skis, bicycles, gliders, boats, helicopter blades. The high fidelity industry has successfully used carbon fibre in pickup arms and to stiffen loudspeaker cones. There is wide potential for carbon fibre composites in a marine environment. Textile machinery components have been successfully made from carbon fibre composites, especially high speed, reciprocating, oscillating and rotating items such as push rods for warp knitting machines, faller bars for grilling machines, actuating linkages, lock sleys. All exploit the good chemical resistance and self-lubricating properties of carbon fibre composites. High performance tyres hav been developed by Dunlop (British patent 1385704) using carbon fibre beading by impregnating carbon fibre in a thermosetting resin, sheathing in a compounded elastomer, and curing both resin and elastomer simultaneously.

THE NORMAL RESPONSE TO INJURY

Implantation of any material requires an assault on epithelium and underlying tissues and it is thus useful to consider the normal process of wound healing before considering in any detail the reponse to carbon implantation.

Following surgical injury new tissue forms by one of three methods.

In repair by resolution, the inevitable response to tissue injury is inflammation. In acute inflammation an exudate of fibrin and polymorphonucleocytes develops secondary to the initial haemorrhage. The strict definition of acute inflammation is the reaction of the vascular and supporting elements of tissue which results in the formation of a protein rich exudate and is followed by a series of changes which are defined as : (a) the vascular response, (b) swelling and exudation with inclusion of the cellular exudate (Phagocytosis) and (c) changes in other tissue components.

The vascular response is an initial vaso-constriction due to mechanical stimulation of the capilleries. It is rapidly followed by vasodilatation and while this can occur in totally denervated tissue, it is centrally influenced by the nervous system. Dilated vessels are in part enlarged by endothelial swelling resulting in leucocyte adherance. The polymorph adherance is a secondary response to exudation of a gelatinous layer from the damaged endothelial cells. This is accompanied by passage of fluid through the cells themselves and that in turn is due to increased vascular permiability to proteins due to increased capillary blood pressure, breakdown of large molecule tissue proteins and increased fluidity of the tissue ground substance. Soon the fluid exudate is followed by a cellular exudate. White cell migration starts with neutrophil polymorphs and is followed by the large monocytes (the macrophages). Lymphocytes are not a feature of acute inflammation. The macrophages engulf foreign material, fibrin, red cells from the initial haemorrhage and if bacteria are present, they too, are ingested at this early stage. Macrophages may join together to form giant cells. The end result of repair by resolution is the restoration of normal tissue and a total removal of all secondary products.

The second response is repair by granulation tissue. This response is characterised by an early appearance of repair by resolution but this ceases at an early stage because of the presence of necrosed cells produced by the initial injury. Macrophages ingest dead tissue cells and may coalesce to form giant cells.

Granulation tissue is formed by the proliferation of the surrounding connective tissue, capillaries, fibroblasts and inflammatory cells. The stage of vascularisation is the initial stage of granulation, and is necessary for the inward movement of fibroblasts which rapidly develop collagenous fibrin around them and thus become mature fibrocytes. Fibroplasia continues and is followed eventually by devascularisation leaving behind the mature collagen which forms a scar.

The third method is regeneration which as its name implies, is similar to resolution but involves a granulation tissue stage before there is proliferation of surrounding undamaged cells and without scar tissue (collagen) formation.

CHRONIC INFLAMMATION AND THE FOREIGN BODY RESPONSE

Since complete healing can only occur when the acute inflammatory and demolition phases are complete, any irritant which cannot be removed results in a continued attempt at healing but with failure of the normal healing process. Thus chronic inflammation is a process in which inflammatory destruction is proceeding at the same time as attempts at healing (Walter and Israel 1963). The prime requirement for chronic inflammation is therefore the continued presence of an irritant. This can be a foreign body, bacteria, or maybe due to secondary effect of material such as steroids which impair the normal acute inflammatory process.

The features of chronic inflammation are thus those of persistent acute inflammation with fluid exudate and macrophage coalescence (giant cells). It must be emphasised however, that the presence of giant cells is a periodic feature of acute inflammation, and only the prolonged presence of giant cells in large numbers is a characteristic of chronic inflammation. Foreign body giant cells are thus the results of macrophage coalescence in response to the presence of a foreign body, and if persistant, indicate incomplete toleration of the foreign body.

TISSUE RESPONSE TO IMPLANTS

The tissue response to implantation of a foreign body varies from the changes seen in association with a surgical (i.e. sterile minimally traumatising lesion) incision to a massive foreign body response. Other later changes such as carcinogenesis secondary to the chemical nature of the implant or its physical form must also be considered.

These will be discussed under the discussion of tissue response to carbon and possible late sequelae following the description of experiments conducted for the purpose of this thesis.

Following implantation of any material, the initial response in the accumulation of polymorphonucleocytes is followed by invasion by macrophages. The most favourable response is one in which there is slight thickening of the scar tissue (that tissue normally seen in repair following small clean surgical wounds) with a thick fibrous capsule developing around the implant. In theory at least, the foreign body is thus rendered extra-corporeal (Calnan 1963). However Charnley (1970) indicates that a slightly more florid response with occasional giant cells is not necessarily indicative of a true foreign body reaction. This is to say that limited numbers of foreign body cells (giant cells derived from macrophages, the large wandering phagocytic cells) are not indicative of lack of inertness in the implant.

OTHER FACTORS INFLUENCING THE FOREIGN BODY RESPONSE

That implants of the same chemical nature may be different in physical form and hence excite a different response based on that physical difference has already been referred to.

The risk of infection is ever present in any surgical procedure.

It is with the basic response of body tissues to injury, their response to foreign bodies and the understanding of differences in tissue reaction to the chemical and physical nature of implanted materials that carbon fibre has been studied as a possible implant material in orthopaedics.

TYPES OF CARBON UNDER INVESTIGATION AS IMPLANTS

Three basic types have been investigated (Figure 1) :

1. Carbon fibre tow - prepared from polyacrylonitrile precursor
2. Carbon fibre reinforced carbon
3. Carbon reinforced plastics

The background to carbon fibre (carbon fibre tow) has already been outlined. This forms the basis of all carbon fibre materials. Carbon reinforced carbon is pure carbon without a plastic reinforcing agent and in solid form has great strength and rigidity. It is stronger than many steels (Jenkins and Kawamura 1976) and has a much slower density. Carbon-reinforced-carbon is a relatively new development and only recently has it become possible to introduce carbon into the interstices between the fibres without causing distortion and without introducing internal strains, sufficient to disrupt the composite. Hill, Walker and Thomas (1973) overcame this problem by dispersing colloidal graphite in the original resin thus lowering the contraction of the resinous binder on carbonisation and thus preserving the integrity of the composite. McLoughlin (1970) has achieved the same using a hydrocarbon gas which is passed through a porous carbon mass at temperatures high enough for one of the many forms of pyrolytic carbon to be deposited. The demands of the aerospace industry for a lightweight material of excellent mechanical property, with low creep, has led to the rapid development of this material. One use is in aircraft brakes and the brake linings of Concorde are now made of this material. The only medical use to date is in the manufacture of heart valves for experimental purposes by Jenkins in conjunction with the

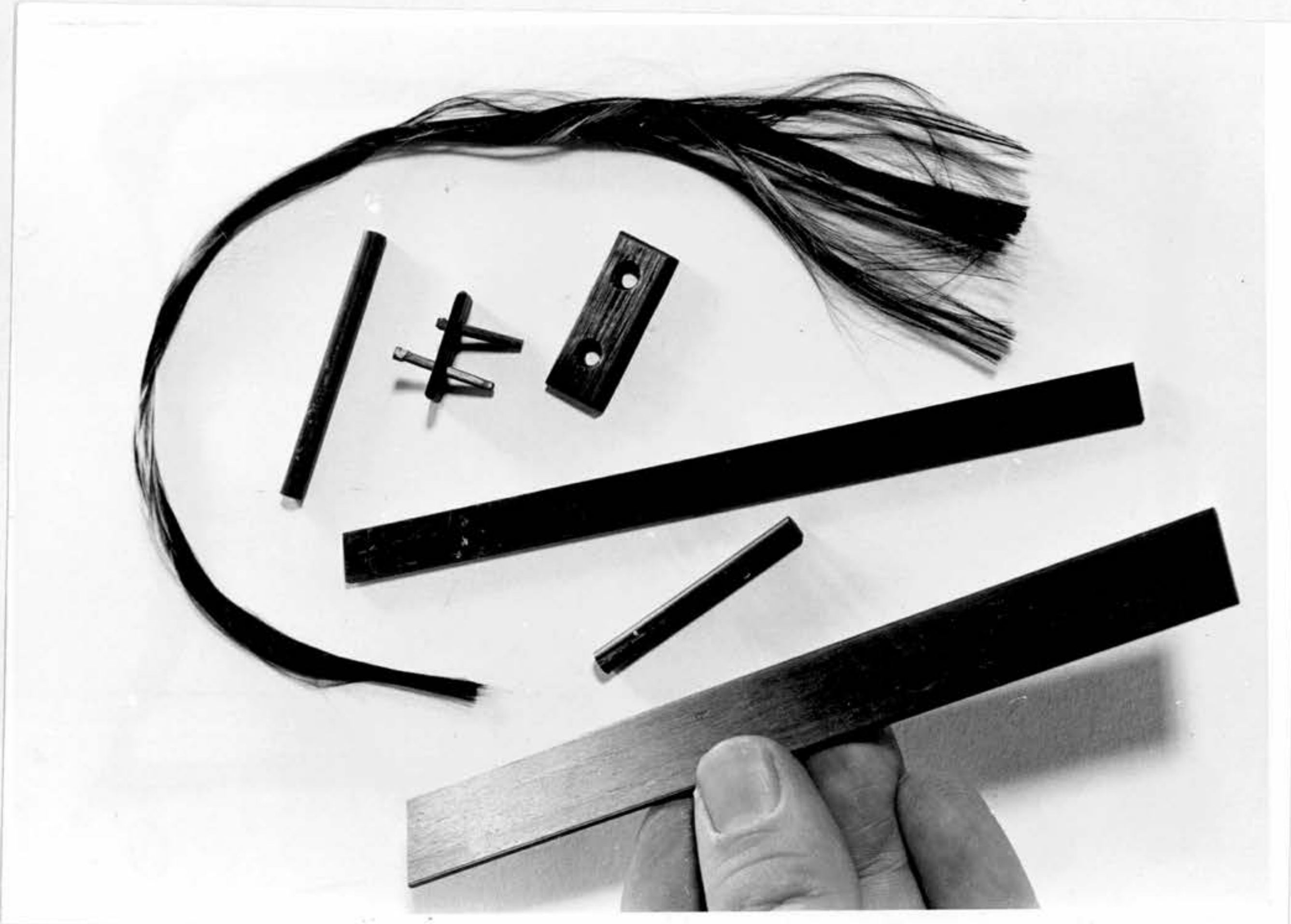


FIGURE 1. DIFFERING TYPES OF CARBON FIBRE

Top Left	:	Carbon Fibre Tow
Centre	:	Carbon Reinforced Carbon
Bottom Right	:	Carbon Composite

Escola Parlista de Medecina (Brazil) (Jenkins and Kawamura 1976).

Carbon reinforced plastics (Gill 1972) have already been referred to. From the medical and surgical point of view while they have great tensile strength and low density, they offer nothing more than conventional metal implants with the added problem of tissue composite surface compatability which largely depends on the nature of the plastic part of the composite. Some composites are already in use particularly in dentistry but low impact strength is a serious disadvantage (Fraunhofer, L'Estrage and Mack 1971).

EXPERIMENTAL INVESTIGATION ON CARBON AS AN IMPLANT MATERIAL

In an initial series of pilot experiments reported by McKibbin (1972) tests were performed using a porous carbon (carbonised lignum vitae) vitreous and glassy carbon and carbon reinforced carbon.

The implants were prepared in the form of small cylinders 3mm in diameter and 6mm in length. These were implanted in the cancellous bone of the upper tibia of adult rabbits.

As controls, similar implants were inserted in the contralateral tibia using either vitallium or stainless steel cylinders manufacturered from conventional surgical implants. In additional animals, longer carbon implants were used which protruded through both cortical surfaces of the tibia and out though the skin on both sides. All the animals were killed at 12 weeks, and the implants removed. The implants themselves and the bony bed in which they lay were examined by routine histological methods. In the case of the porous implants the bone implant interface was studied with the Scanning Electron Microscrope to reveal any evidence of vascular invasion of the surface. Naked eye examination of the control metallic implants showed no evidence of erosion. Histological examination of the bed showed no inflammatory reaction but a thin fibrous lining membrane had developed around the implant which was rather more marked in the case of stainless steel.

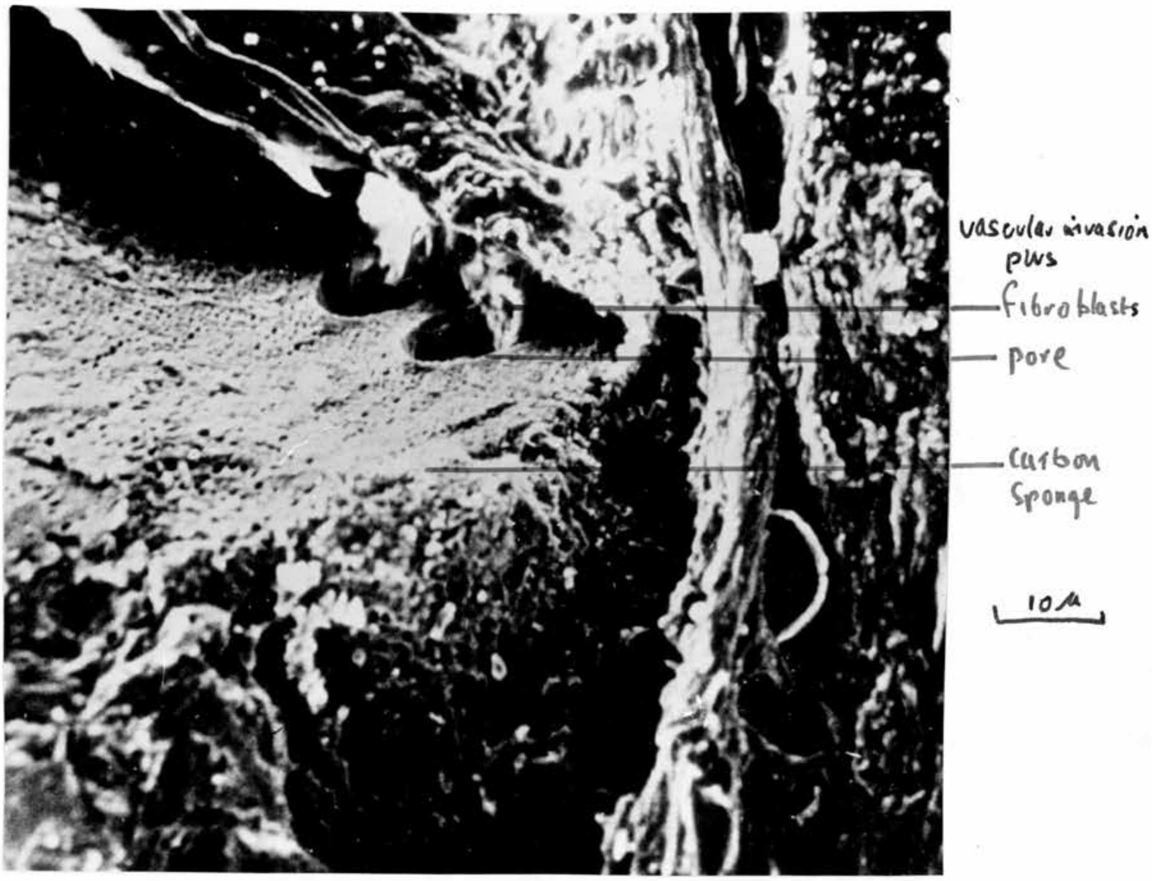
With the carbon implant, the behaviour was different between the porous and solid materials. The solid implants (fibre reinforced and glassy carbon) were easily liberated from the bone to which they had formed no attachment and their surfaces showed no erosion. Examination of the bed showed no inflammatory change and only faint traces of a limiting membrance such as had characterised the metal implants.

The porous implant was quite different. This was firmly attached to the bone and could only be removed with difficulty. The bed showed no inflammatory changes but it was evident that the implant was undergoing a process of piecemeal removal. Small carbon fragments could be seen as intracellular inclusions and some larger fragments had provoked a giant cell response. The scanning electron microscope study showed clear vascular invasion of the surface pores (Figure 2).

In the case of of the carbon implants which had been left protruding from the skin, it appeared on initial outward inspection as though these had disappeared. However, further examination revealed that the epithelium had actually grown completely over the ends of the implants, so burying them. The skin was found to be quite adherent to the carbon.

On the basis of this preliminary short term study it appeared that the carbon materials tested were well tolerated by the tissues and produced significantly less reaction than accepted metallic implants.

Of the materials used, the carbon-reinforced carbon appeared to be the most promising as a surgical implant because of its remarkable strength while the porous implant had demonstrated that it would become incorporated in local tissues. The material was insufficiently strong and suffered actual physical breakdown by vascular invasion followed by the phagocytic removal of the particles, thus rendering it unsuitable



<u>FIGURE 2</u>

Scanning electromicrograph of surface of porous carbon showing ingrowth of fibroblasts into pores in the carbon sponge.

in that particular form for further consideration as an implant in orthopaedics.

The final experiment in which it was found that carbon would permit growth of epithelium was of interest. This property is not generally shared by metals and it was felt that if it could be confirmed, it would raise a number of possibilities for the use of intero-external implants where adherence of the skin at the point of emergence of the implant would reduce secondary infection and loosening.

From these initial pilot experiments, two factors emerged in relation to the porous carbon. The first was that there was a limited giant cell response of such a minimal nature that carbon in this form had the appearance of an inert material and that while it certainly excited the usual response associated with any injury, the limited number of occasional giant cells suggested that there was little response to the implant itself. The second observed response was that fibroblasts readily proliferated around and through the carbon sponge, indicating that far from promoting encapsulation, the material appeared to encourage tissue to develop through and within the carbon matrix. It is from this work that the series of experiments described originated.

The remarkable purity of vitreous carbon and its potential biological significance was initially suggested by Benson (1971). This material has been investigated with some success. Mooney and Hartman (1973) attempted to suspend a limb prosthesis using a silastic cylinder faced with vitreous carbon. The implant demonstrated the satisfactory seal at the skin interface but the two prostheses implanted were removed at six months because of chronic infection in the bone, rather than chronic at the skin interface. From the observations of satisfactory skin carbon interface healing, Mooney, Hartman, McNeal and Benson (1974) have developed a system of permanent percutaneous electrical connection system using pure carbon. Others (Kadefors and Reswick 1970) have carried out similar experiments with similar results.

Dental implants have been manufactured and used with success and Grenoble (1973) has reported over 100 satisfactory implants with no infection. Similar results have been reported by Von Fraunhofer, L'Estrage and Mace(1971). Using a different form of rigid carbon Kenner, Williams, and Eatherly (1973) described the totally inert nature of graphite following implantation into rabbit femurs.

Carbon composites were initially assessed by the North American Rockwell Corporation (1969) and a suggestion was made that such composites were chemically and physically compatible with fluids and tissue of the human body. More recently Woo, Akeson, Lebenetx, Coutts, Matthews, and Amiel (1974) have demonstrated some promise in the use of carbon composites as alternative materials in the manufacture of internal fixation plates. (Figure 3).

The rapidly developing interest in the last few years in the use of rigid carbon prompted the suggestion that there might be specific advantages in the use of carbon over the conventional implant systems.

The weakness of graphite and the brittle nature of vitreous carbon appear to preclude their use as weight bearing and supporting structures, but the excellent mechanical properties of carbon composites and carbon

FIGURE 3. Carbon composite bone plates

reinforced carbon, together with their suggested high degree of bio-compatibility suggested that further examination was justified.

In the design on the experiments to be described, the basic rules adopted were that any alternative to conventional metallic implants must not only achieve the same results, but there must also be further advantages which would suggest that the carbon implant represented an improvement over the metallic implants in use. Thus, in the case of the bone plates, it is a basic requirement that the plates must be able to support the fracture and yet further advantages must be demonstrated before a realistic claim for the introduction of carbon plates over metal plates can be made.

Theoretically, carbon in rigid form, offers three possible advantages over metal:

1. Bio-Compatibility - The work of others so far described suggest that carbon is particularly compatible with body tissues. The experimental work later described on flexible carbon supports this suggestion.

2. Epithelialisation - Epithelialisation of a foreign material is unusual and has been used in the experiments later described to demonstrate a further example of the peculiar biocompatibility of carbon. The clinical appeal of a material which is rigid, foreign, yet acceptable and which encourages epithelialisation over the surface, lies in its possible use in plate form in the support of fractures of long bones where skin and soft tissue are not readily available .

3. Elastic Modulus - The elastic modulus of living bone is $1-3 \times 10^6$ p.s.i. (Curry 1970, Swanson 1971, Dempster and Liddicoat 1952). Carbon fibre composites have already been established in limited use as space fillers and their biocompatibility demonstrated (Homsey and Anderson 1976). Carbon-reinforced carbon can be manufactured with slightly differing degrees of elasticity, depending on the nature of the carbon matrix and plate thickness (Jordan 1976). Similarly carbon composite (carbon-reinforced plastics) can be readily manufactured to have an elastic modulus similar to that of living bone (Hastings and Thanh-Thuy 1976). Metals are considerably more rigid than human bone and consequently the load bearing characteristics of a system of implant plus tissues will be changed. In fracture plating, it is recognised that some bone resorption occurs because the bone no longer carries its normal load, even after healing occurs. Refracture near the ends of the plate is a hazard of rigid internal fixation and the protagonists of this method of fracture treatment suggest that all rigid weight bearing implants should be removed once fracture healing has occured. (Muller, Allgower and Willenegger 1970). The attraction of a system of plates for rigid internal fixation, which acts as successfully as the standard metal plates now in common use but which have a similar elastic modulus to bone and which therefore do not necessarily have to be removed, is clear. Woo, Akeson, Levenetz, Coutts, Matthews and Amiel (1974) in one series of experiments on radial fractures in dogs, have indicated that the theoretical advantages are borne out in practice.

The experiments described in this thesis examine the theoretical advantages noted with particular attention to epithelialisation and weight bearing in fracture healing.

The experimental work is not complete, nor are the findings as conclusive as that described in the experimental work on flexible carbon.

Where further developments are indicated, the future experiments planned are also indicated in the appropriate sections.

EXPERIMENTS

EXPERIMENT 1.

In order to examine the possible epithelialisation of carbon plates, in each of twenty-one sheep the tibias were exposed on the anterior surface by a 9cm incision. Periosteum was incised and the plates laid on to bone. On thirteen legs in each group, plates made either of titanium, carbon reinforced carbon, or Epoxy based carbon composite (60% epoxy resin by volume, dry weight) were screw fastened. Plates all measured 10cm x 1.3cm x 0.3cm and were perforated by 0.3cm drill holes every 1.5cm. All plates were fastened with two titanium screws one at either end, which passed through the plate and both bone cortices. Wounds were left open and no attempt was made to cover the centre part of the plate. The ends of the plate and end screw holes were covered by the method of making the initial incision slightly shorter than the plate (Figures 4 and 5).

No immobilisation was used and after one week, no attempt was made to keep the wound clean. It was anticipated that all wounds would become infected. This last factor was designed to examine epithelialisation under the most adverse conditions and to mimic the clinical situation of the compound fracture associated with skin loss.

Results

At three days, all animals walked normally. At two weeks there was evidence of healing around the proximal and distal ends of both carbon composite plates and carbon reinforced carbon plates. At one month,

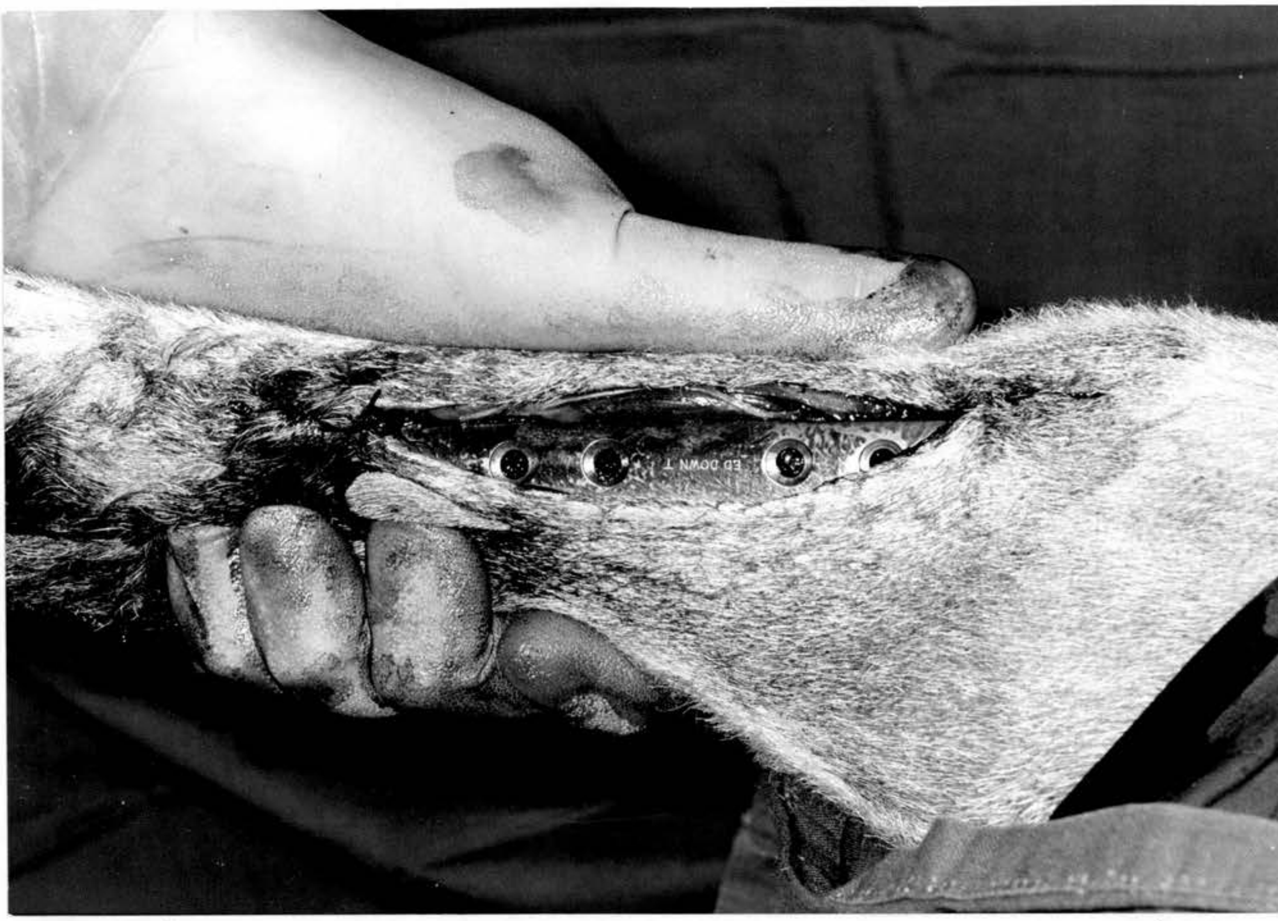


FIGURE 4. Titanium bone plate on tibia of sheep

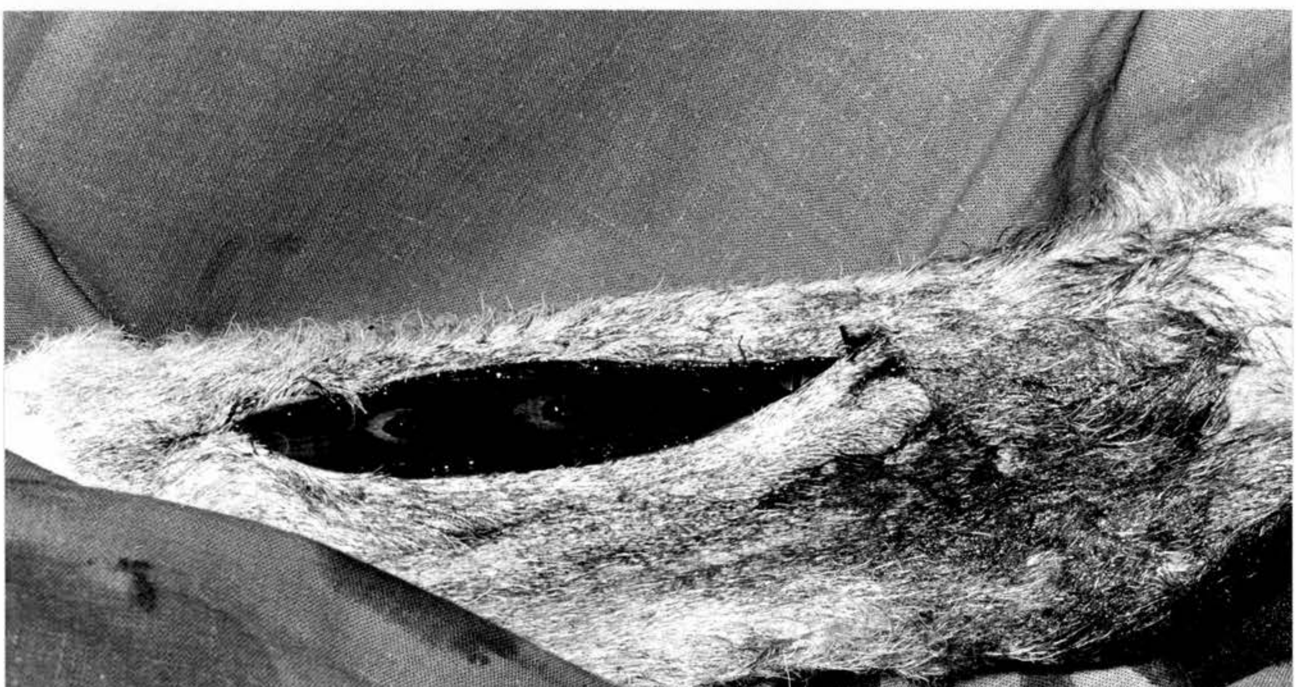


FIGURE 5. Carbon reinforced carbon plate on tibia of sheep

epithelialisation of six of the carbon reinforced carbon plates and four of the composite carbon plates was observed.

At two months, epithelialisation of all carbon reinforced carbon plates and ten carbon composite plates was observed. Epithelialisation of three titanium plates was also seen.

At three months all plates including the metal plates had some degree of epithelialisation. At four months all carbon plates of both types were buried and new normal epithelium with wool growth had occurred. At six months, all plates, including the metal plates, were covered. Infections had occurred periodically throughout the six months period in all groups with partial wound breakdown and subsequent slow regeneration of epitheleum (Figures 6 and 7).

The results indicated that epithelialisation would occur in sheep in all types of rigid implants examined. However, the fastest rate of epithelialisation was seen in the pure carbon (carbon-reinforced carbon) and slowest in the metal plates. From this experiment the conclusion was drawn that if carbon reinforced carbon plates could be manufactured in such a way that they had practical use and provided an equally good support, they might, because of the demonstrated effects of early and apparently preferential epithelialisation, have value in fracture management.

FIGURE 6. Typical result at three months following implantation of titanium plate

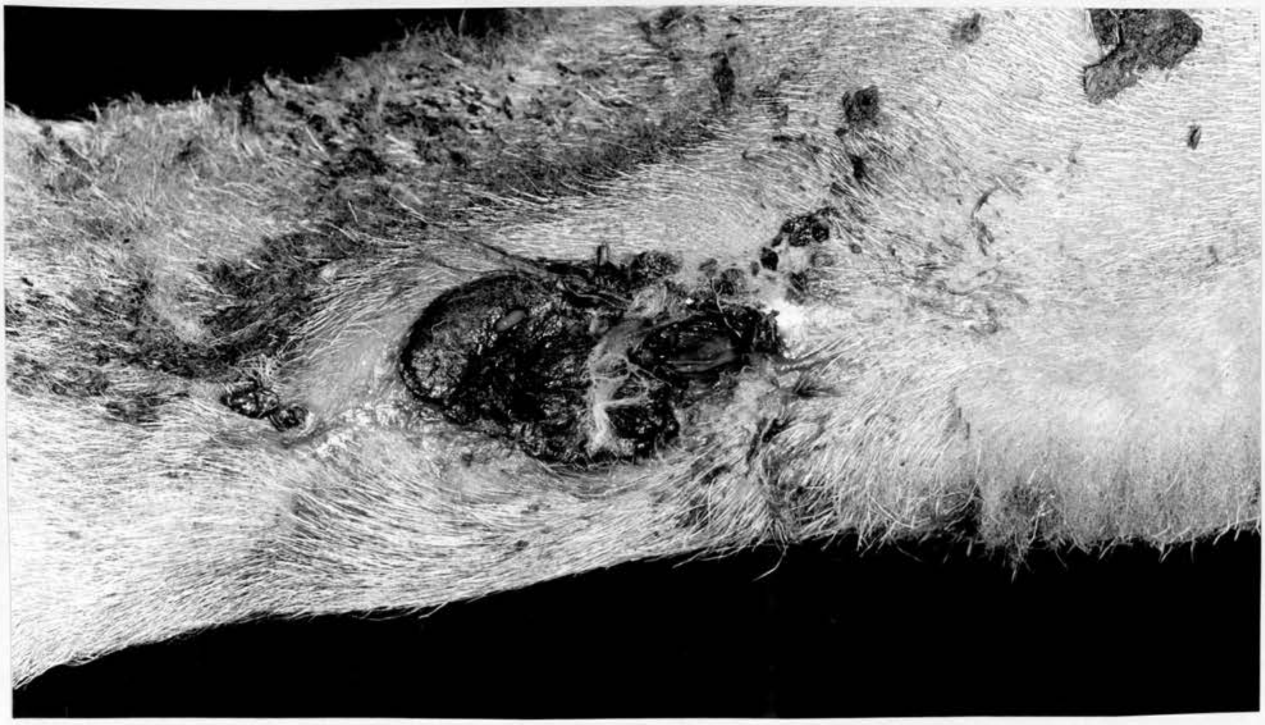


FIGURE 7. Typical result at three months following implantation of carbon-reinforced-carbon plate

EXPERIMENT 1 (A)

In six adult sheep, a one inch carbon reinforced carbon plate was fastened by a single titanium screw to the tibia exposed through a suitable incision.

At six months, marsupialisation had occured in four of the six and total epithelialisation in the remaining pair. These results correspond to the unpublished experiences of Mooney and provide the suggestion that epithelialisation or marsupialisation are related to the size of the implant. In the earlier experiment in which larger implants were used,the outcome was one of epithelialisation but in smaller implants it appears that marsupialisation is the normal response to the exposed implant. (Figures 8 and 9).

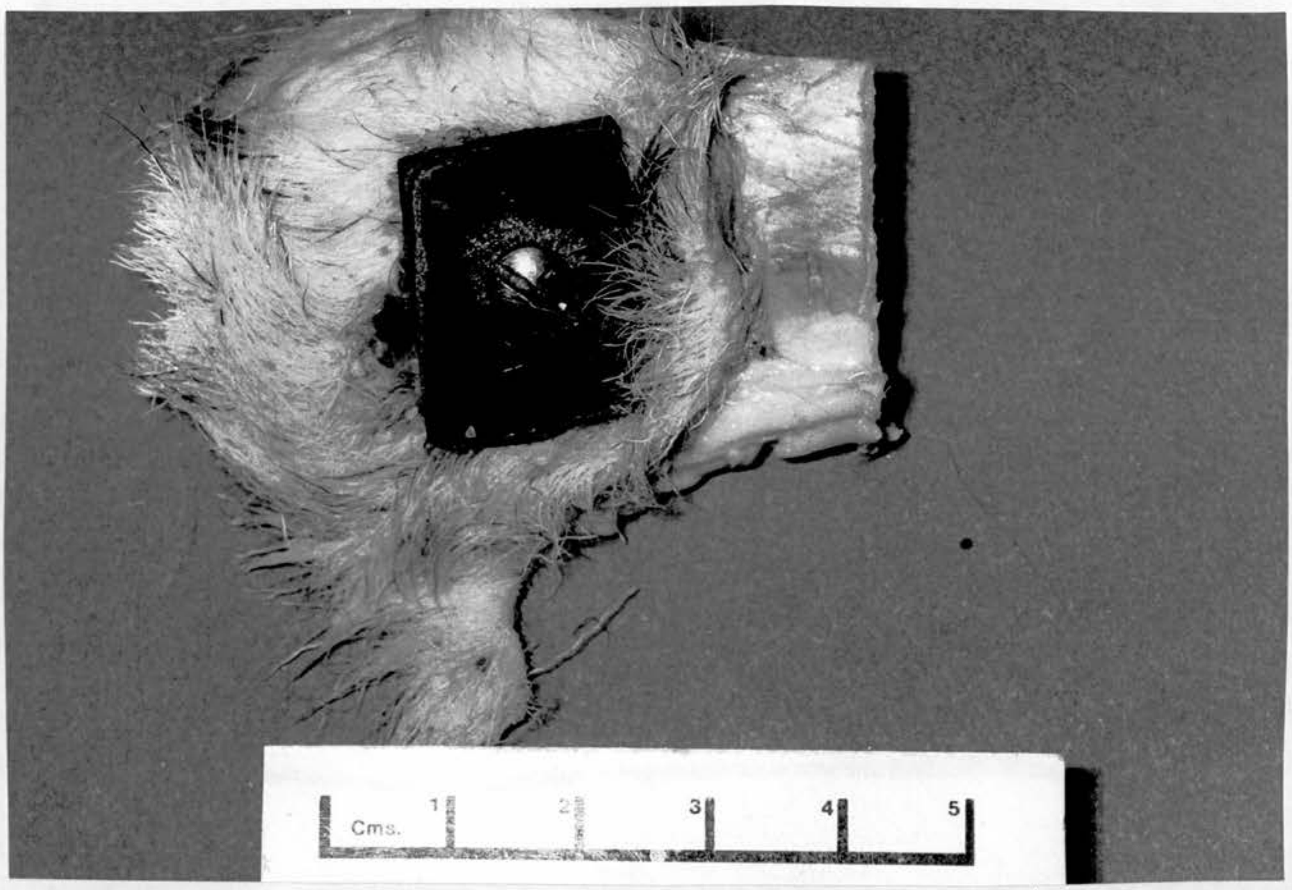


FIGURE 8. Marsuplialisation of a one-inch square of carbon reinforced carbon on the sheeps tibia.

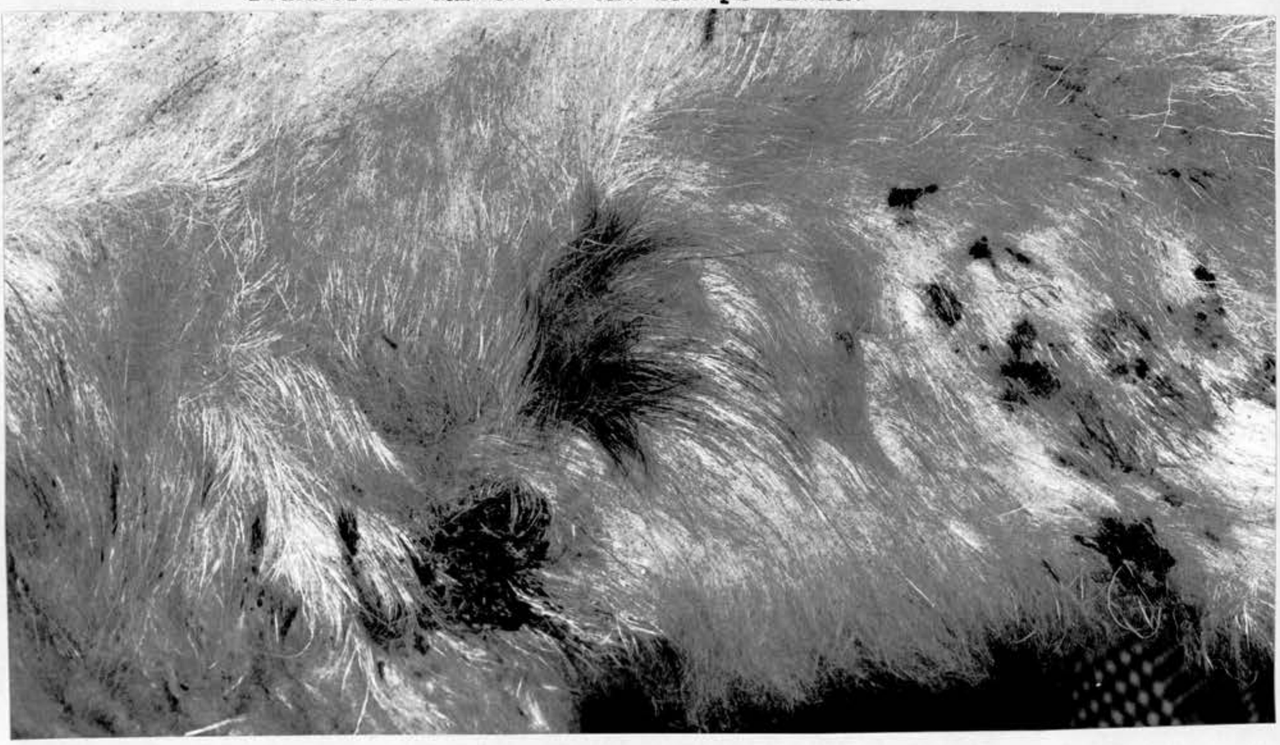


FIGURE 9. Epithelialisation on a one inch square of carbon reinforced carbon on the sheeps tibia showing new epithelial growth with hair.

EXPERIMENT 2

In order to examine the apparent acceptance of carbon by epithelium, experiments of the nature described by Mooney, Hartmann, McNeal and Benson (1974) were performed. Their experiments had been designed to demonstrate the use of vitreous carbon as a percutaneous electrode, and they had demonstrated infection free percutaneous passage of carbon with high epithelial adhesion.

In twelve rabbits, carbon reinforced carbon rods 0.4cms diameter and 4.0cms in length were passed through the shaved skin and subcutaneous tissue overlying the thoraco-lumbar juntion, and allowed to protrude approximately 1.5cms. on either side. (Figure 10)

Six control rabbits were similarly prepared using similar sized stainless steel rods.

All carbon rods remained in place and at one month, there was evidence of epithelialisation in that the rods had apparently become adherant to surrounding skin (Figure 11). All metal rods became infected at the skin rod interface and fell out spontaneously.

At periods between four and six months, the apparent epithelial adhesion of the carbon rods broke down, and the rods fell freely from their implanted site. Following removal of the rods, there was black staining of the edges of the hole through which the rods had passed. Histological examination of the skin edges showed that the black staining was due to carbon particles and that there was little evidence of a foreign body reaction. The implication was drawn that the failure of epithelialisation over a prolonged period was due in part to the

FIGURE 10. Carbon reinforced carbon rod protruding through the skin over the dorsal vertebrae of the rabbit.

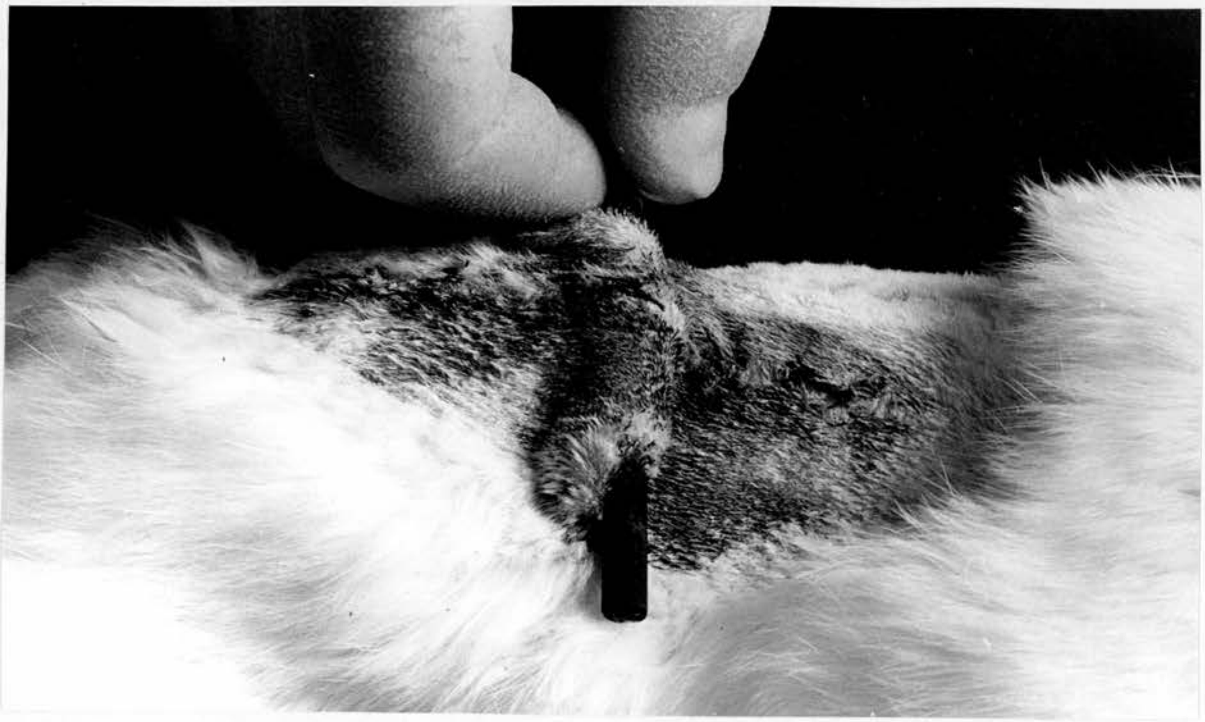


FIGURE 11. The appearance at three months in which tissue adhesion is demonstrated by turning the rod.

mechanical severance of the skin carbon interface, and due also in part to fragmentation, destruction or collapse of the outermost part of the carbon implant as evidenced by the presence of carbon particles in the skin. It is suggested that when there is no movement of epithelium about the exposed implant , the epithelial adhesions are sufficient to permit further epithelial growth, but movement will eventually encourage collapse of the carbon epithelium interface.

EXPERIMENT 3

Clinical tests were performed using carbon reinforced carbon rods 15cms in length by 0.4cm in diameter, manufactured in the manner of steinman pins in the management of fractures by the established intero-external bracing fixation or skeletal traction methods, in order to determine whether the early epithelialisation of the rods observed in the rabbit could be used to overcome the frequent problem of metal-skin interface breakdown with pin track infection.

In four elderly females with fractures of the femoral shaft, carbon reinforced carbon Steinman pins were passed through the tibial tubercle and tractions applied.

Although carbon reinforced carbon pins have great strength, they are also brittle, and sudden and violent movement, which, had the pins been made of metal, would have resulted in deformation and bending, resulted in carbon reinforced carbon pin fracture.

In another three patients, the pins held but there was no evidence of epithelialisation and in all patients, pin tract infection intervened.

In two elderly male patients with severely comminuted supracondylar fractures, carbon reinforced carbon pins 15cms. in length x 0.8cms. in diameter were passed through the femur and tibia, proximal and distal to the fracture site and held in methylmethacrylate supports in the established manner of treatment where metal Steinman pins are normally used. In both patients the pins held satisfactorily but in both, pin tract infection of a mild degree developed (Figure 12).

From these preliminary clinical tests, it was concluded that the movement of the skin against the carbon had prevented epithelialisation and no advantage in the use of carbon reinforced carbon pins in the situations described were seen.

EXPERIMENT 4

In order to examine the potential value of carbon reinforced carbon plates and carbon composite plates in comparison with the stainless steel plates, experiments were performed on fractures of the femur in sheep. The work of Woo, Akeson, Levenetz, Coutts, Matthews and Amiel (1974) had suggested that advantage was to be gained in terms of less secondary osteoporosis following fixation of fractures with plates of elastic modulus closer to that of bone than rigid stainless steel plates. One major criticism of their work may be made because the radius (used in their experiments) is supported to some extent by the ulna and is probably not the most suitable bone for experiments on fractures in the diaphysis of a weight bearing bone. With this in mind

FIGURE 12. Double pairs of carbon reinforced carbon pins used to temporarily support a comminuted supracondylar fracture of the femur. Pin track infection followed necessitating their removal.

it was felt that the most severe test of fracture support would be in the long bones of the hind limb of a heavy animal.

Six hole plates were prepared from carbon reinforced carbon and from epoxy based carbon composites with a modulus of elasticity in both plate types, close to that of adult bone (range 1-3 x 10^6 PSI). Similar size six hole plates were prepared from stainless steel and used as controls. In each of six adult sheep, the femur was fractured at its mid point after weakening with six double cortex holes drilled at the appropriate point. The fracture fragments were then opposed in an anatomical position as possible, and the fragments held without compression, supported by the plates described. In the case of stainless steel plates, stainless steel screws were used, and in the carbon plates, titanium screws. Following closure of the wound, no attempt was made to provide further support of the fracture, and animals were allowed to weight-bear freely from the earliest post operative time. Routine antibiotics were used postoperatively for five days.

Results

Radiographs were taken at one month intervals up to five months when all animals were killed.

At one week, all animals were able to bear weight and all walked using all four limbs.

In all groups, fracture healing had progressed with large amounts of callus formation. In all groups the fixation proved to be imperfect. In the carbon reinforced carbon group all fractures had healed radiologically by three months. In four of the six animals, there had been marked movement at the fracture site and in the other two, some movement was also seen. Histological examination showed florid callus and carbon staining of the neighbouring soft tissues. Giant cells were seen in all specimens examined.

Similar changes were seen in the carbon composite group.

The stainless steel group also showed mal-position. There was no evidence of metallic fragment staining and no evidence of metallic fragment deposition, but giant cells were similarly seen in all specimens examined.

In summary, there was no difference in the rate of fracture healing in any of the groups examined. However, it was concluded that the poor quality of fixation as demonstrated in this severe test of different materials, in use as internal fixation devices, negated any worthwhile conclusions. The carbon-reinforced-carbon and carbon composite plates had produced no worse results than the stainless steel plates, but the marked movement prior to healing in all groups, together with the massive callus formation, made worthwhile assessment impossible.

FUTURE EXPERIMENTS

It was felt that the model used was a severe test for different types of internal fixation, but equally so, it was the satisfactory model since any advance in material usage and possible advantages in materials in practise, has to be examined under the most stringent and testing conditions. At this time, arrangements have been made with the Atomic Weapons Research Establishment at Aldermaston for the preparation of carbon-reinforced-carbon and epoxy based carbon composite plates of similar elastic modulus to that of bone, but exact copies in shape and form to the ASIF plates made of stainless steel in common clinical use (Muller, Willenegar and Allgower 1970). It is planned to examine the relative merits of the two types of carbon plate in comparison with stainless steel plates of proven type, both on a long and short term basis, with particular care being taken in the techniques used. It is anticipated that it will be possible to determine whether the theoretical advantages of the carbon-reinforced-carbon plates exist over the conventional metal plates.

In order to determine whether the apparent promise of epithelialisation is due to the surface properties of pure carbon, a series of plates have been designed and are being prepared by the Atomic Weapons Research Establishment in which established stainless steel ASIF plates are being coated with carbon. These will be used in sheep to support fractures of weight bearing long bones in which the skin and soft tissues overlying the plate will be excised. In this way, a plate of proven design and established load bearing capacity will be used, inserted by an established technique, but with a different surface coating, and it will then be possible to test the surface properties in a fracture situation.

EXPERIMENT 5

Lack of success due to technical failure of the implant led to the suggestion of intra medullary fixation with carbon rods. If the special properties of an elastic modulus similar to that of bone would lead to alteration at the rate of fracture healing, a system in which rigid fixation could be achieved might show the differences anticipated.

In twenty adult rabbits, the diaphysis of the femur was fractured and supported with a suitable diameter carbon reinforced carbon or metal rod (0.4 - 0.6cm diameter) by insertion through the skin overlying the greater trochanter and led down through the medullary canal to a point approximately 0.5 cms from the knee joint. All rods were left protruding 1cm through the skin at the proximal end. No post operative mobilisation was used.

All animals were able to weight bear within three days and were able to move normally within ten days.

Examination of the specimens was made at three months. The only difference observed at the fracture site was that in the carbon-reinforced-carbon group, there was a greater degree of callus formation than in the stainless steel group. In all the rods were firmly held and were only withdrawn with difficulty.

The implication was drawn that the greater flexibility of the carbon had led to greater movement of the fracture site with the resultant greater degree of callus formation. Since no difference in the rate of fracture healing was observed, no comment could be made on this respect.

The observation was also made that new bone growth had readily occurred in eight of the ten carbon reinforced carbon group around the end of the distal pole of the carbon rod, inside the medullary canal. (Figure 13). This finding was not seen in any of the metal group. It is tempting to imply that carbon had stimulated new bone growth by virtue of its presence, although it may have been due to movement at the distal end of the rod. The observation was also made that in all the carbon reinforced carbon rods left protruding through the skin at the proximal end, epithelialisation over the rods had occurred. (Figure 14). This was not observed in any of the metal rods. The previously noted epithelialisation of carbon when used as a plate, was thus confirmed in this experiment.

EXPERIMENT 6

In any method of fixation in the treatment of fractures, not only is the nature of the plate itself important, but also the method by which the plate is held to the bone. It is conventional to use screws of the same material as the plate.

In the first series of experiments, screws made from carbon reinforced carbon were manufactured by turning a thread on a suitable rod of carbon (Figure 15). Although the standard preparation of carbon reinforced carbon rods has great strength in two dimensions, in the third, it is comparatively weak. Thus, all threads failed from collapse and were therefore of little use (Figure 16). An alternative method of

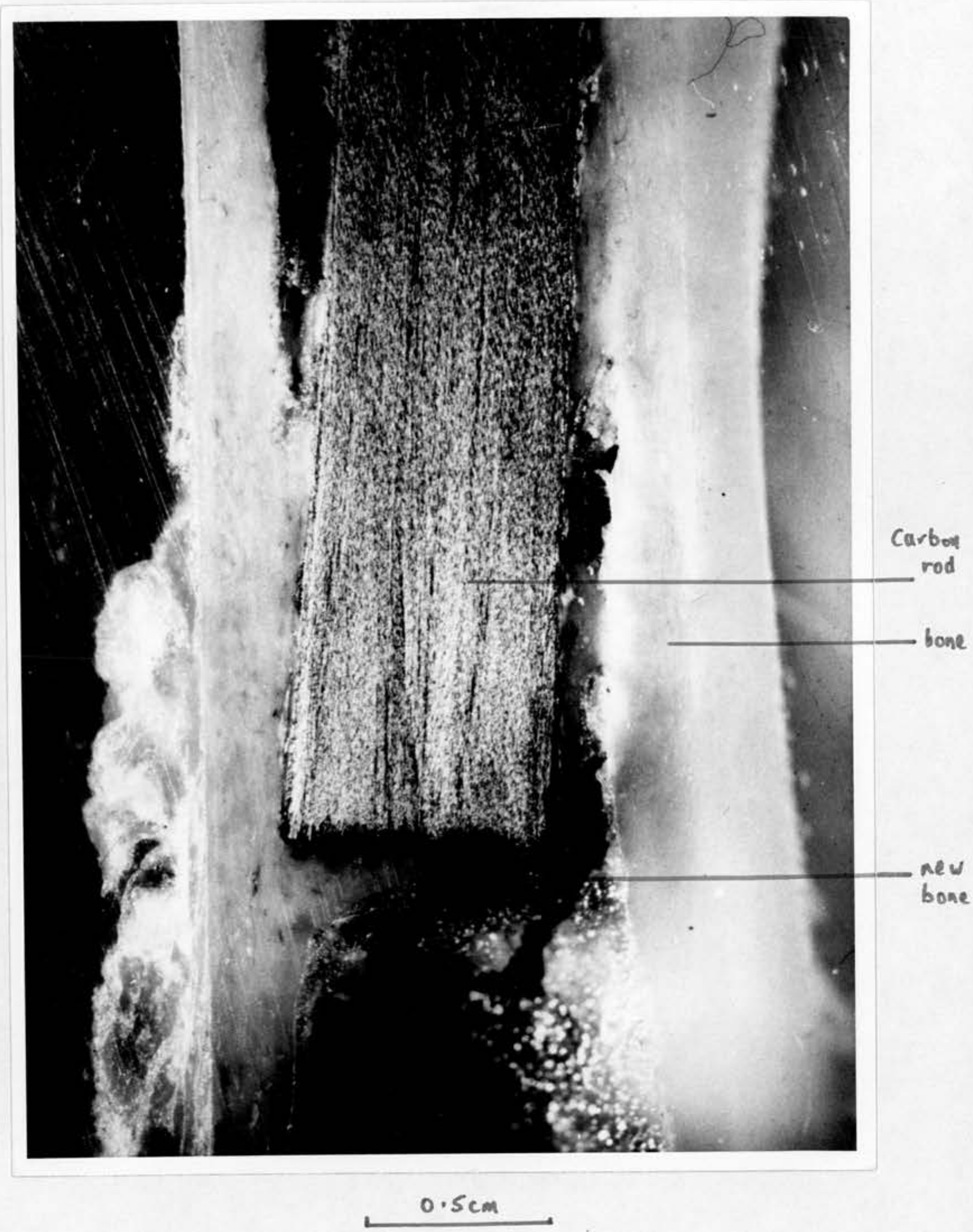
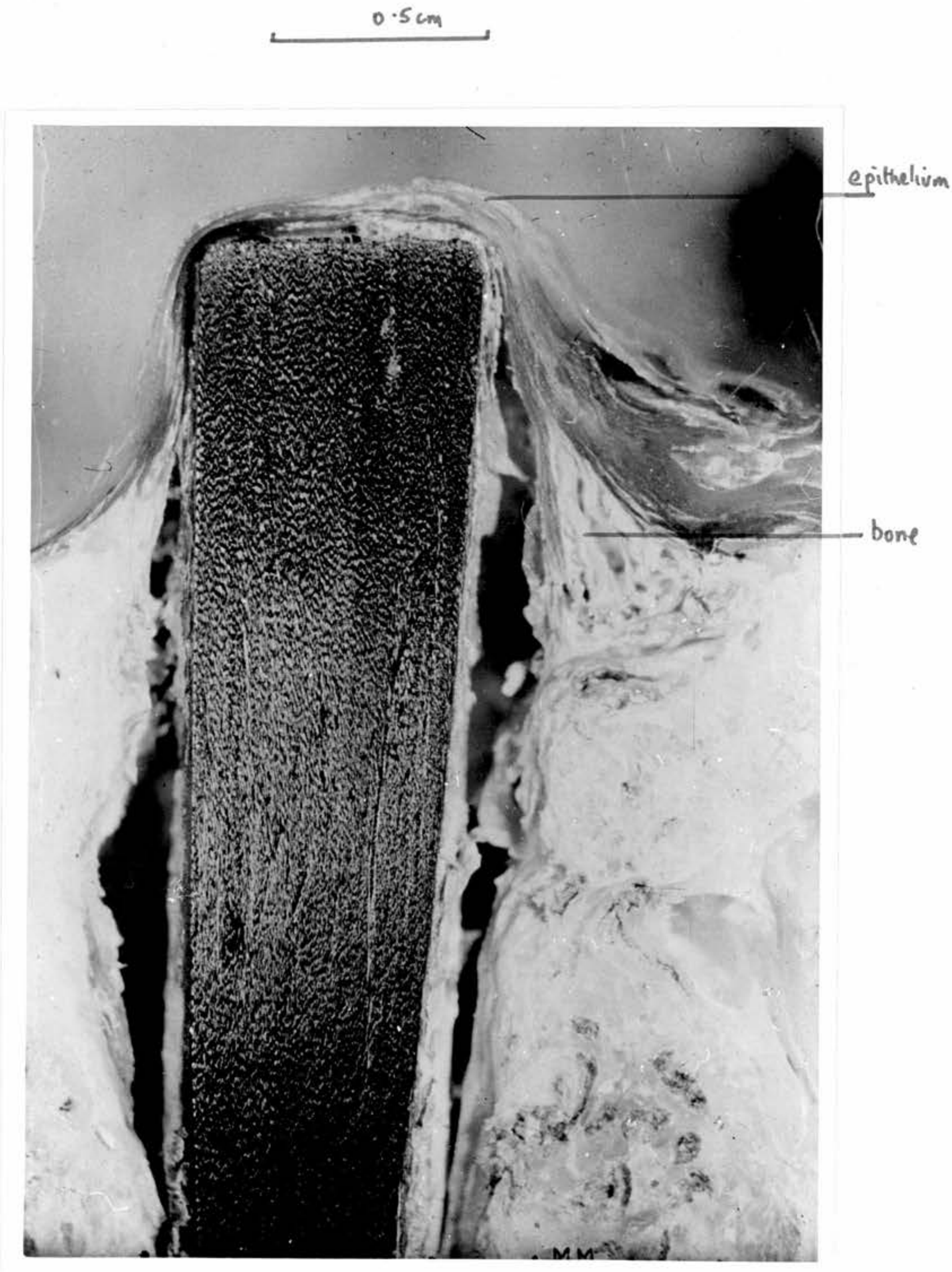


FIGURE 13. New bone growth is seen at the distal end of the carbon intra medullary nail. This feature was not observed in any of the metal implant animals. Specimen shown at three months post implantation.

FIGURE 14. Cross section of the proximal end of the rabbit femur in which the carbon rod has been left protruding 1.0 cm. Epithelialisation is clearly demonstrated.



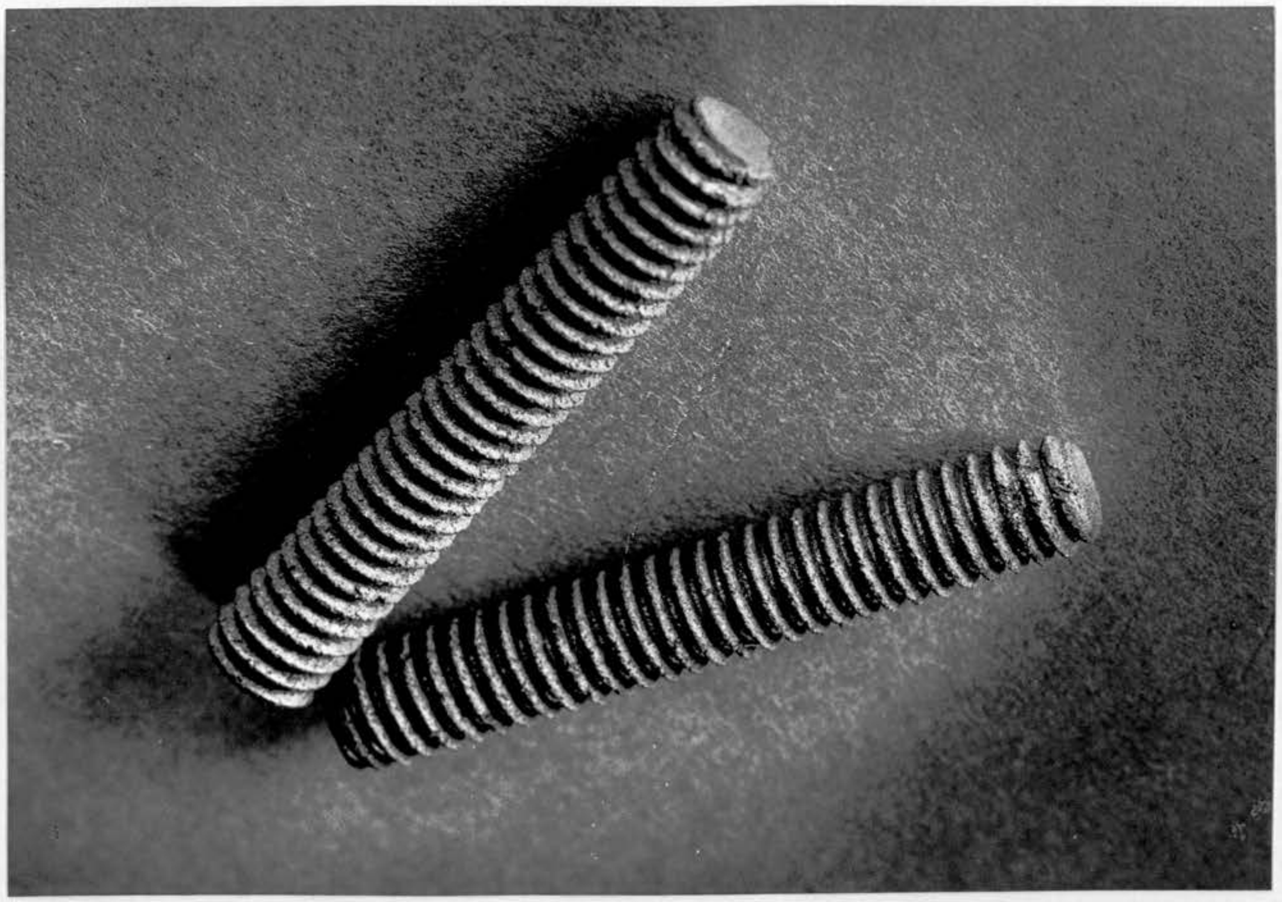


FIGURE 15. Threads prepared on carbon rods in an early attempt to prepare carbon screws.

2·0 cm

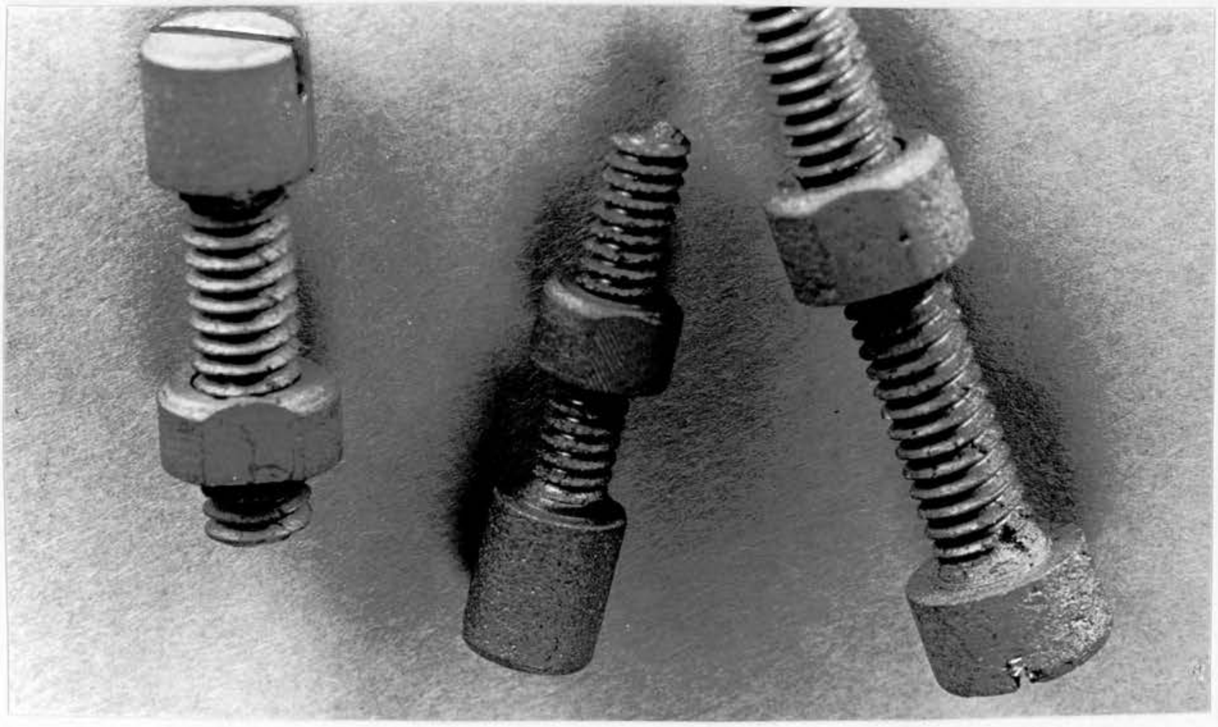


FIGURE 16. Typical collapse of the threaded carbon reinforced carbon screws and bolts.

thread preparation led to strong thread but weak screw shafts and so far it has not been possible to manufacture suitable screws of this type.

There is some evidence to suggest that there is no necessity for exact matching of different parts of an implant even when they are in close proximity. Mears (1976) has shown that selected dissimilar alloys can be used together without the risk of galvanic corrosion. In view of the difficulty in the preparation of suitable screws from carbon, two alternatives have been examined.

A series of galvanic cells were prepared in which similar and dissimilar materials were suspended in saline at a constant 20°C and the EMF recorded between the anode and cathode (Figure 17). The accompanying graph (Figure 18) shows that carbon with any one of the standard metals used in orthopaedic screw manufacture produces no greater EMF than the metals alone, suggesting that Mears observation (Mears 1976) applies to carbon with these metals and also suggest that it is not neccesary to have screws made of carbon when carbon plates are in use. However, the screw heads will have their own surface properties and the suggestion has been made that carbon encourages epithelialisation at a greater rate than conventional metals. Using the techniques of the Atomic Weapons Research Establishment, it is now possible to coat titanium screws with carbon in such a way that the whole screw is encased in carbon, including the head. (Figure 19).

It is planned to investigate the use of such screws when ASIF pattern carbon coated plates and carbon plates are available from the

FIGURE 17. Galvanic cells in which the anode is prepared from carbon reinforced carbon and the cathode from a standard implant metal. Metal to metal cells were also examined.

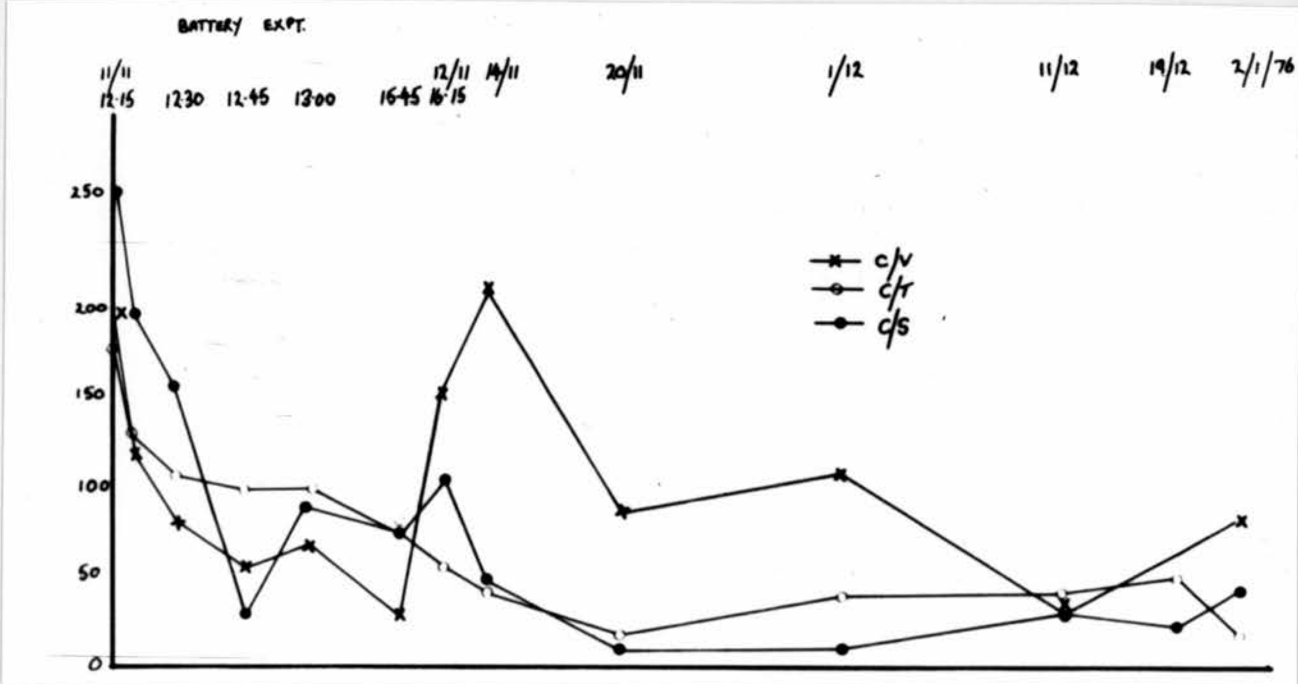


FIGURE 18. Carbon/Vitallium (C.V); Carbon/Titanium (C.T.); and Carbon/Steel (C.S.) All records with measurements recorded in saline after stabilisation for 48 hours at 20°C on each occasion. Recordings were made over a period of seven weeks. Abscissa time and ordinate microvolts.

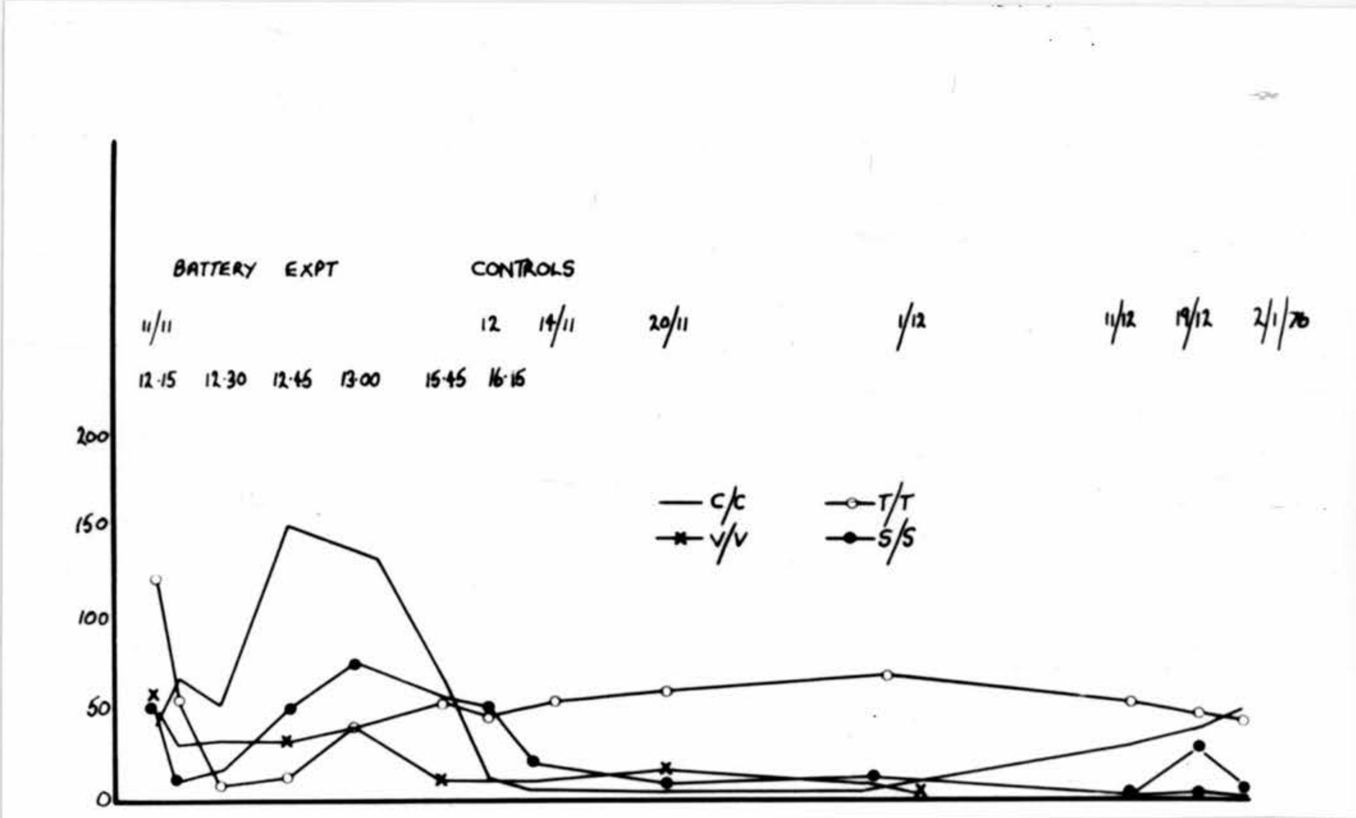


FIGURE 18 (a) As is figure 18.

CC : Carbon-Carbon VV : Vitallium-Vitallium

TT : Titanium-Titanium SS : Steel-Steel

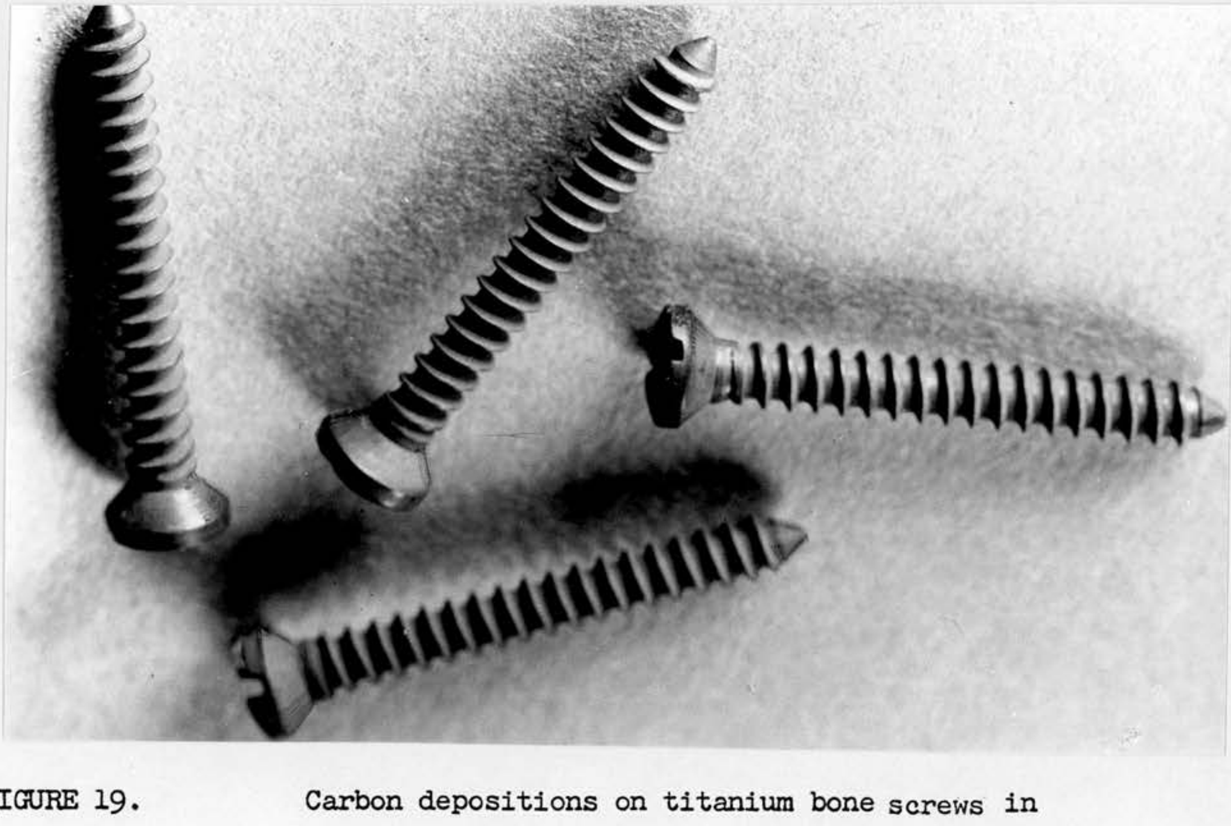


FIGURE 19. Carbon depositions on titanium bone screws in order to overcome galvanic effects and reduce corrosion potential.

0.5cm

Atomic Weapons Research Establishment.

The difficulty experienced in the preparation of suitable plates and screws described, led to the search for alternative uses of carbon and in this, flexible carbon was thought to hold some promise. The first problem encountered with the rigid plates, namely that of suitable fixation, was thought not to be an insurmountable problem with flexible fibre. Secondly, while there are adequate alternatives to the use of carbon plates, there are some human situations where a strong, yet pliable, strand of material of biologically inert nature would have a place. In situations such as tendon replacement, support of a joint with lax ligaments and extra capsular joint support, an entirely satisfactory alternative to tendon or ligament homograft is still to be determined. With this particular aim in mind, the properties and potential use of flexible carbon have been explored.

EXPERIMENTS CONDUCTED ON FLEXIBLE CARBON FIBRE

1. Commercially available carbon fibre tow

Definition

The flexible carbon examined initially was that made by Courtaulds Limited, Coventy, U.K. (under the trade name of "Grafil"). This is prepared from polyacrylonitrile precursor and is made in three basic forms: High Strain, High Tensile Strength, and High Modulus. In crude terms, the high strain variety is less brittle than the high modulus type.

Mechanical properties of Carbon Reinforced Carbon Fibre			
Property	Unidirectional	0-90° Cross Ply	Cloth Fibre Sandwich
Flexural Modulus Longitudinal GN/m^2 Transverse GN/m^2	 140.0 7.0	 60.0 60.0	 60 8
Flexural Strength Longitudinal GN/m^2 Transverse MN/m^2	 1.2 15.0	 50.0 -	 0.65 70.0
Interlaminar Shear Strength MN/m^2	18.0	18.0	20.0

Normally all three fibre types are supplied surface treated as denoted by the letter S. The surface treatment modifies the fibre surface by the use of Epolite resin (designated Courtaulds 628/MNA/K61B - Shell). Finally an epoxy resin binder is added to aid handling.

EXPERIMENT 1

In ten rats, high modulus carbon fibre tow was used as a suture material in the repair of abdominal incisions. Control animals were treated in the same way, except that abdominal wounds were repaired with standard silk sutures. Immediately, the unsuitability of this particular type of flexible carbon for this particular use was demonstrated because the relatively inflexible nature of the high modulus carbon led to breakage during knotting. All wounds broke down due to collapse of the carbon.

It was concluded that where a high degree of flexibility was required, the high modulus strength carbon was unsuitable on grounds of lack of flexibility of the material.

EXPERIMENT 2

The same model was used but this time AS (high strain) carbon tow was used. Like the high modulus strength carbon, this is prepared and presented as a tow of 10,000 individual parallel fibres. Poor knotting characteristics were again noted, but in those in which the carbon tow was woven through the skin, rather than tied directly in the manner of a suture knot, the carbon held until the wound had healed.

Rats were killed at ten and twenty days, and tissue examined histologically. The silk suture and woven silk controls were similarly killed. The normal response to silk sutures, that is evidence of the normal healing reaction already referred to above, together with occasional micro-abcesses and a florid foreign body giant cell response was observed in all. In the woven carbon repaired abdominal wounds there was ready growth of fibrous tissue into the interstices of carbon tow, but as with the silk sutures, foreign body giant cells were frequently seen. In order to test whether this response was a feature of the commercially available carbon fibre tow, non-surface treated, non epoxy sized carbon tow of high strain was specially prepared and examined in a further experiment.

EXPERIMENT 3

Using the same model but with the inclusion of rabbits as well as rats, the untreated tow was compared with the standard treated tow. In order to be certain that the resin binder had been totally removed, all carbon was washed with acetone to remove any trace of the resin.

The gross physical results were the same in that all wounds in both rabbits and rats held when the carbon fibre was woven across the wound rather than tied. Histological examination showed different responses to the two types of high strain fibre.

In the standard surface treated fibre, the same giant cell response was seen. However, in the untreated acetone washed fibre, whilst fibrous tissue readily grew into the interstices of the carbon metrix there was practically no giant cell response at all. This was found to be true in rabbits and rats, thus excluding the chance of species specificity reactions to this type of carbon.

Animals were killed at ten, twenty and forty days and in each case, the results were similar.

Since it is established that the appearance of occasional giant cells is a feature of healing in the presence or absence of the most inert materials, it was concluded that this initial evidence of a carbon tow as an inert material was correct.

It was felt that a reaction to this type of carbon, similar in every way to that seen with pure carbon sponge, was worthy of further investigation.

For the first time, it appeared that the advantages of the inert nature of pure carbon demonstrated in the early pilot experiments with carbon of no physical strength, could be used with advantage in this particular type of carbon which did possess high physical strength.

EXPERIMENT 4

High strain carbon fibre unsurface treated and washed in acetone has been used in all further experiments with flexible carbon. In this form, it is stated by the manufacturers to be more than 99.5% pure carbon.

In twenty rabbits the tendo achilles was excised from its musculo tendinous origin to its bony insertion in the os calcis. All operations were performed with rabbits anaesthetised with Nembutal 0.5kg/kg per body weight and have been performed under sterile conditions.

A suitable sized hole was drilled through the os calcis in a horixontal direction and carbon fibre threaded through it. The carbon was next passed through the musculo tendinous site approximately 1cm above the site of proximal excision. Each strand of carbon fibre was passed from either side and back on itself and finally held with two silk sutures in such a way that the tendon was replaced with a double strand of carbon fibre tow of the correct length.

Following closure, no immobilisation was used. Since rabbits cannot walk satisfactorily on three legs, it was felt that non-immobilisation would be a severe test of the mechanical integrity of the tendon prosthesis.

All animals were able to support weight on the operative side within two days and all walked and hopped normally at ten days. Rabbits were killed at ten, twenty and forty days and the tendo achilles replacement examined.

At ten days, there was evidence to the naked eye of white fibrous tissue development at both proximal and distal ends of the implant. By twenty days, the implant was totally enveloped by fibrous tissue. By forty days, it appeared to the naked eye that a new tendon had formed around the implant (Figure 20).

Histological examination of the carbon tendon prosthesis at ten days taken one centimetre from the bony insertion showed there to be new development of white fibrous connective tissue interposed around and throughout the carbon fibre matrices. (Figure 21). At the centre, the individual carbon filaments were still densely packed together but there was some infiltration by fibrous tissue. Sections taken at the mid-point of the prosthesis showed a lesser degree of

FIGURE 20. Neo-tendon induction around the carbon tendo achilles replacement in the rabbit at 40 days post implantation. The carbon has been totally enveloped with new tendon like tissue of similar bulk to the normal tendon.

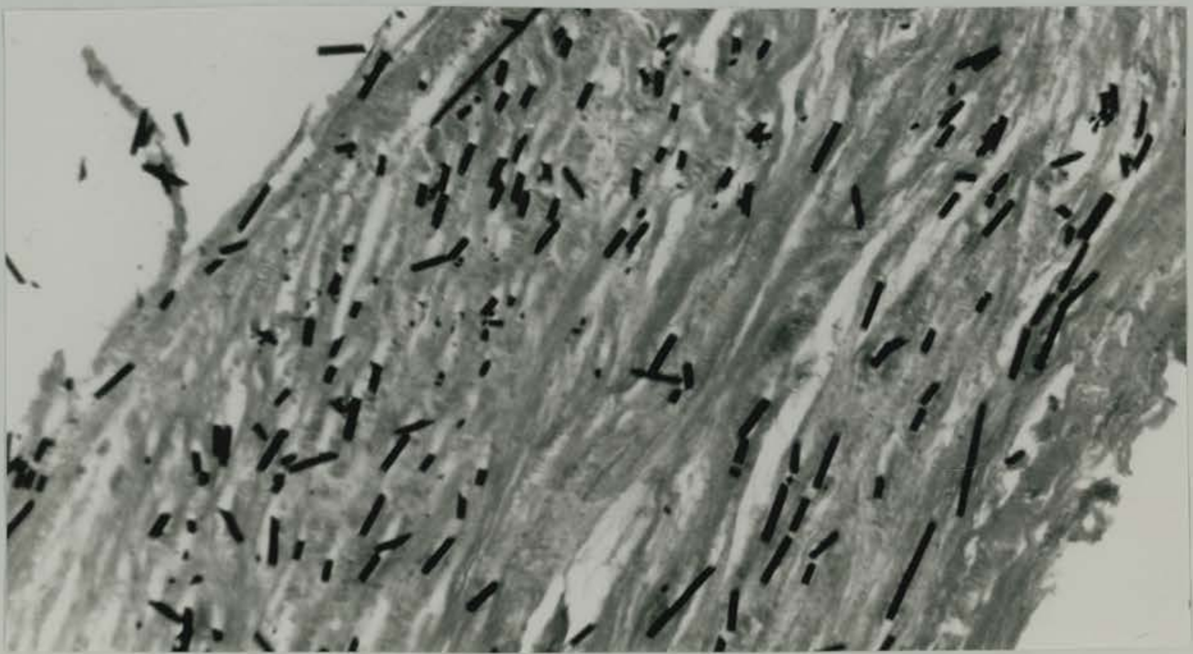


FIGURE 21 Histological appearance of the neo tendon showing separation of the carbon filaments and neo tendon induction 4o days post implantation. (x 80. H&E.)

fibrous infiltration.

The implication was drawn that new tendon tissue was developing along the carbon prosthesis from either end.

Examination of the six week specimens, which to the naked eye were totally buried in neo tendon, showed similar findings to the ten day specimens but with two differences. First, the new tendon had enveloped and had grown throughout the whole carbon matrix throughout the entire length of the carbon prosthesis, and secondly, the individual carbon fibres were separated to a greater degree than in the earlier samples.

The implication was drawn that not only had the presence of the carbon induced new tendon to form throughout its length, but that there was an ongoing process exemplified by the continued stimulus to the development of new tendon throughout the carbon matrix.

EXPERIMENT 5

In order to test whether the new tendon was functioning as a tendon (other than naked eye evidence of normal function and animal mobility) and to determine whether the apparently newly induced tissue had active strength of its own, measurements of the breaking strain of the new tendon were performed.

In fifteen rabbits, the same model was used and animals killed at varying intervals up to six weeks. In each, the normal tendon from the opposite side was used as a control and breaking strength determined by the simple method of adding weight to the distal part of the toally excised muscle-tendon-bone unit.

Figure 22 shows that the breaking strain of the normal tendon in the adult rabbit under investigation varied between 10 and 20 kg. Initially the carbon prosthesis broke at 2 kg. strain, but the strength rapidly increased until at 4 weeks it had achieved a strength equal to that of the opposite side. This corresponded with the earlier observation that new tendon developed from either end and when total envelopment and intra matrix growth had occured, the new tendon achieved normal strength.

EXPERIMENT 6

Although evidence existed which suggested that the growth had occurred from either end towards the centre, in the development of a new tendon, a further series of experiments were conducted to determine whether this statement was correct.

In four rabbits the same experimental model was used with replacement of the tendo achilles but the carbon prosthesis was totally enclosed in a polythene tube in such a way that the whole carbon implant was separated from surrounding tissue, thus preventing growth of new tendon from adjacent soft tissue and only allowing growth from either end.

Examination of specimens removed at six weeks showed that there

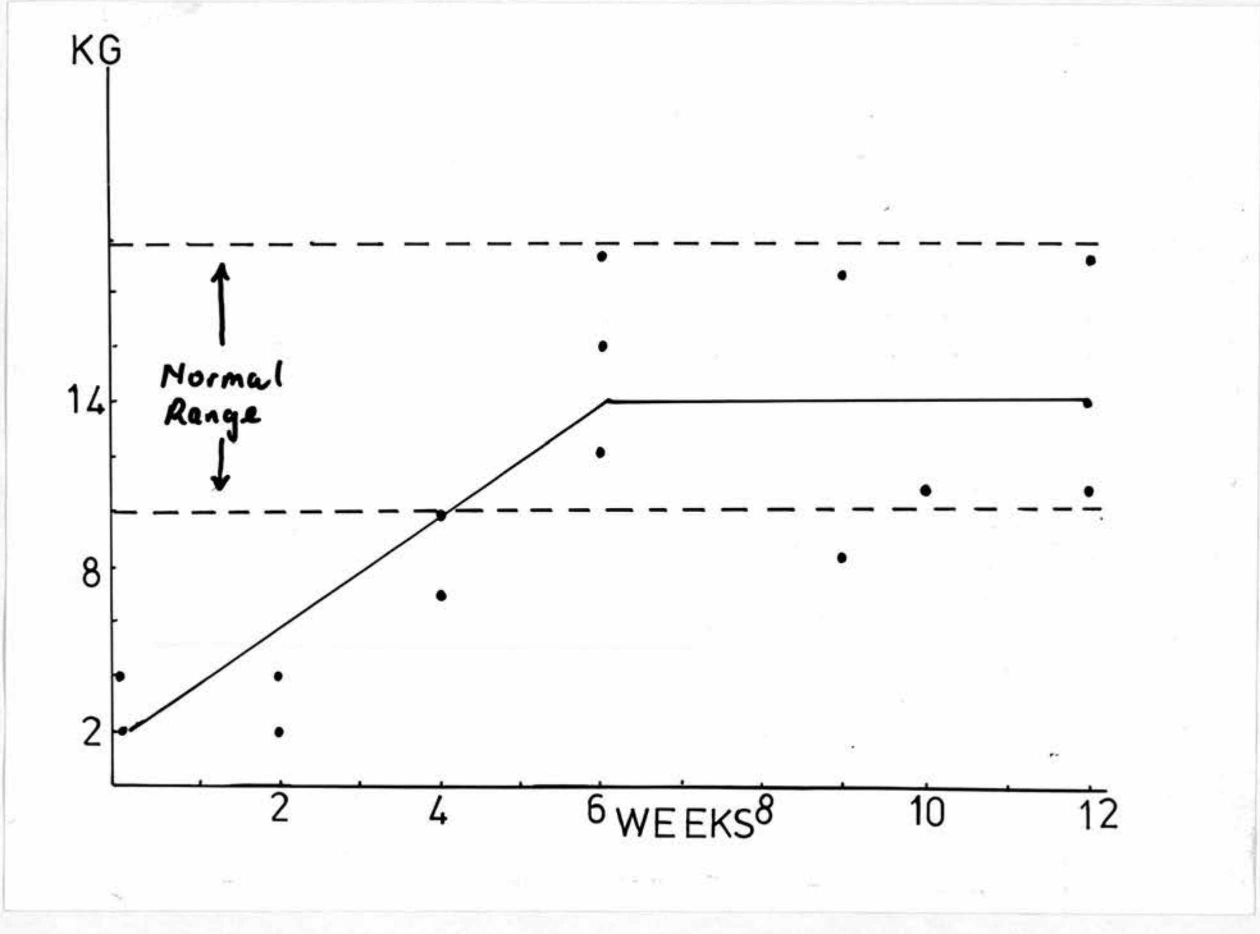


FIGURE 22.
ref page 90, para 2.

was limited growth towards the centre from either end, but that the carbon in the central part of the tube remained uncovered. Histological examination of the carbon tendon interface showed that there was some early separation of the individual carbon filaments, suggesting that the same process of collagen development seen in other experiments was progressing. This pilot experiment which suggested, but did not prove, that tendon growth could occur from the ends only, was replaced by a new experimental model in which the cruciate ligaments were replaced. (See Below.)

EXPERIMENT 7

Tendo Achilles Replacement in Sheep

In twenty sheep the tendo achilles (Figure 23) was excised and replaced with carbon in a similar manner as that used in the rabbits. (Figure 24). In view of the increased weight of the sheep compared with that of a rabbit, three strands of non-surface treated, non resinated, acetone washed, high strain carbon (10,000 individual 8 micron diameter filaments) were taken and plaited to form a cord-like structure. The resulting plait was led through a suitable hole in the os calcis and back through the musculo tendinous origin to form a double strand of plaited carbon of the same length as the original tendon. The musculo tendinous fixation of the implant was reinforced by weaving the carbon through the musculo tendinous insertion and held by two stout silk sutures. The distal fixation through bone was achived by tying the carbon upon itself.

Following closure, no immobilisation was used.

FIGURE 23 The normal sheep tendo achilles

FIGURE 24. The sheep tendo achilles excised and replaced with a double strand of flexible carbon fibre tow.

In a further series of four groups of three sheep each, the tendo achilles was excised and replaced with a double loop of plaited mono-filament nylon, a similar loop of silk, and a loop of plaited Dexon (polyglycolic acid). In the final group, no replacement material was used following excision.

Results

(a) Carbon Group

All animals walked fully weight bearing on the operated side within a week. At four weeks, all animals could run and by six weeks, the gait was normal. In one animal the wound became infected and the animal was killed at six weeks. Four sheep were killed at three months, five at six months, and five at one year. The remaining five were left for two years.

Histological examination of the carbon implant and surrounding tissue was performed on animals at three months, six months, and twelve months post operative periods.

Naked eye examination at three months showed a bulky mass of new tendon like tissue which totally enveloped the carbon implant. (Figure 25). While the new tendon was adherent to surrounding fat, it was sufficiently mobile within the fat to allow a full range of movements at the ankle joint.

Histological examination of the central part of the implant showed appearances similar to those in the rabbits seen at six weeks. The carbon had become totally enveloped in tendon tissue and growth had

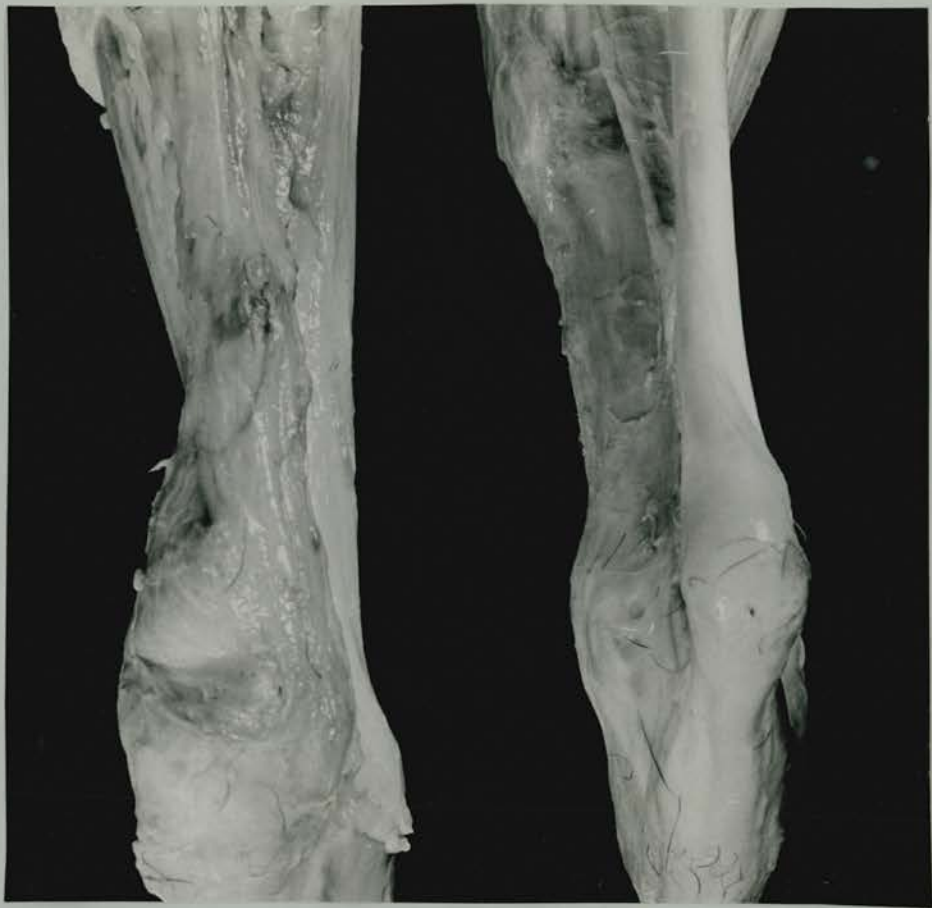


FIGURE 25. The normal sheep tendo achilles (right) and the neo tendon induced by carbon implantation at three months (left)

FIGURE 26. The normal anatomical appearance of the tendo achilles in the sheep at six months post implantation. Carbon can be seen at the distal insertion where it has purposely been exposed during disection.

occurred throughout the carbon matrix. The tissue had the histological appearance of normal tendon. It was noted that at the edge of the implant, the individual carbon filaments were separated, but in the centre, while growth had occurred throughout, the individual fibres were still closely packed together.

Naked eye examination at six months showed the tendon to be slightly less bulky and approximating in shape and form to that on the opposite side. (Figure 26). A full range of movement was noted at the ankle.

Histological examination of the six months specimen showed a similar appearance but whereas in the three months specimen the central part of the implant had only been slightly separated, at six months, central ingrowth into the carbon matrix had apparently further separated the individual filaments. (Figure 27).

The Para aortic lymph nodes were examined in all sheep from six months onwards (Figure 28). At six months the nodes on the carbon implants were darker in colour to naked eye examination, and slightly larger than on the non-implanted side. A peripheral ring of dark material was noted. This change was only observed in the most proximal group of nodes. The nodes on the opposite appeared normal.

Histological examination of the nodes proved to be difficult since, while simple sectioning of the nodes showed the nodes to be darkly stained, (Figure 29), preparation of a thin section by embedding in parafin wax and microtome cutting, resulted in loss of all dark stained material. Despite repeated attempts it proved impossible to hold more than a fraction of the dark material in the thin section. However, when the

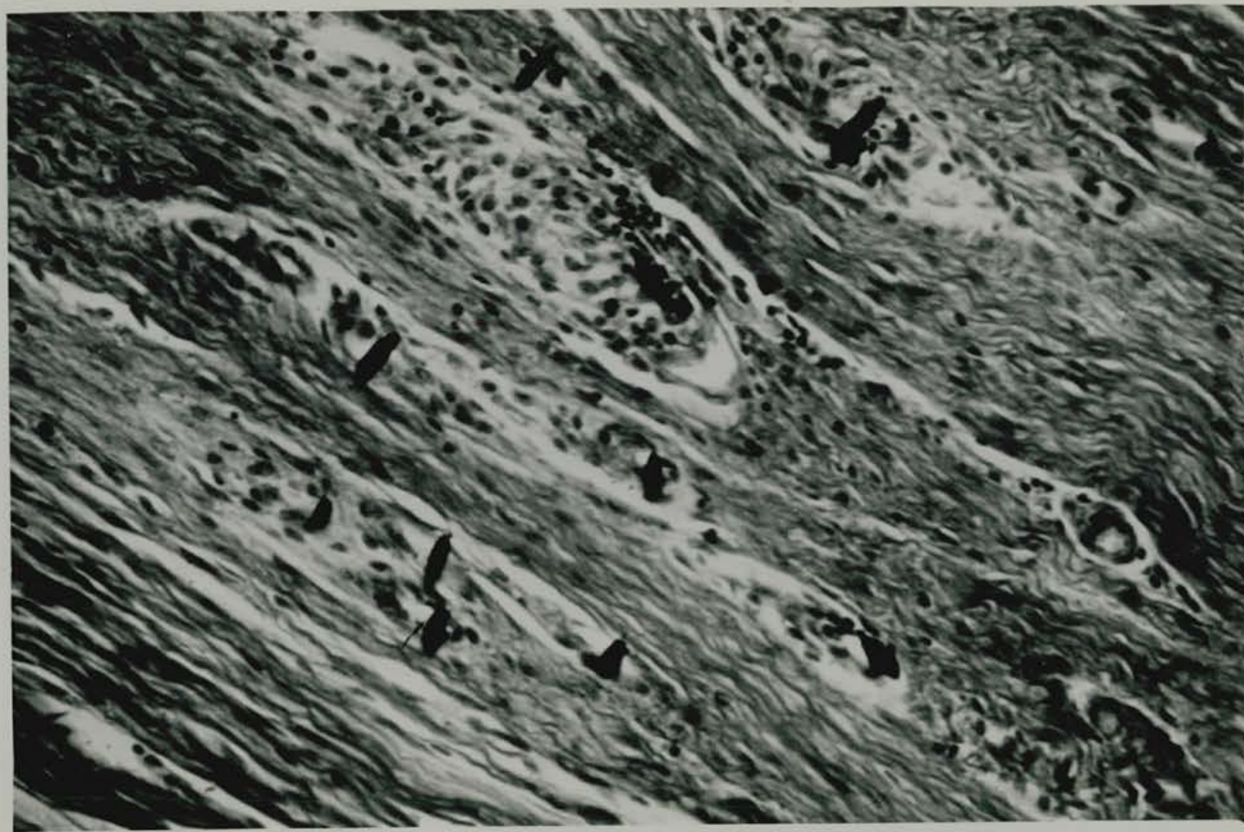


FIGURE 27. The characteristic appearance of the neo tendon six months post implantation. The separation of the carbon fragments and the development of the newly induced collagen is clearly seen. (x 100 H&E)

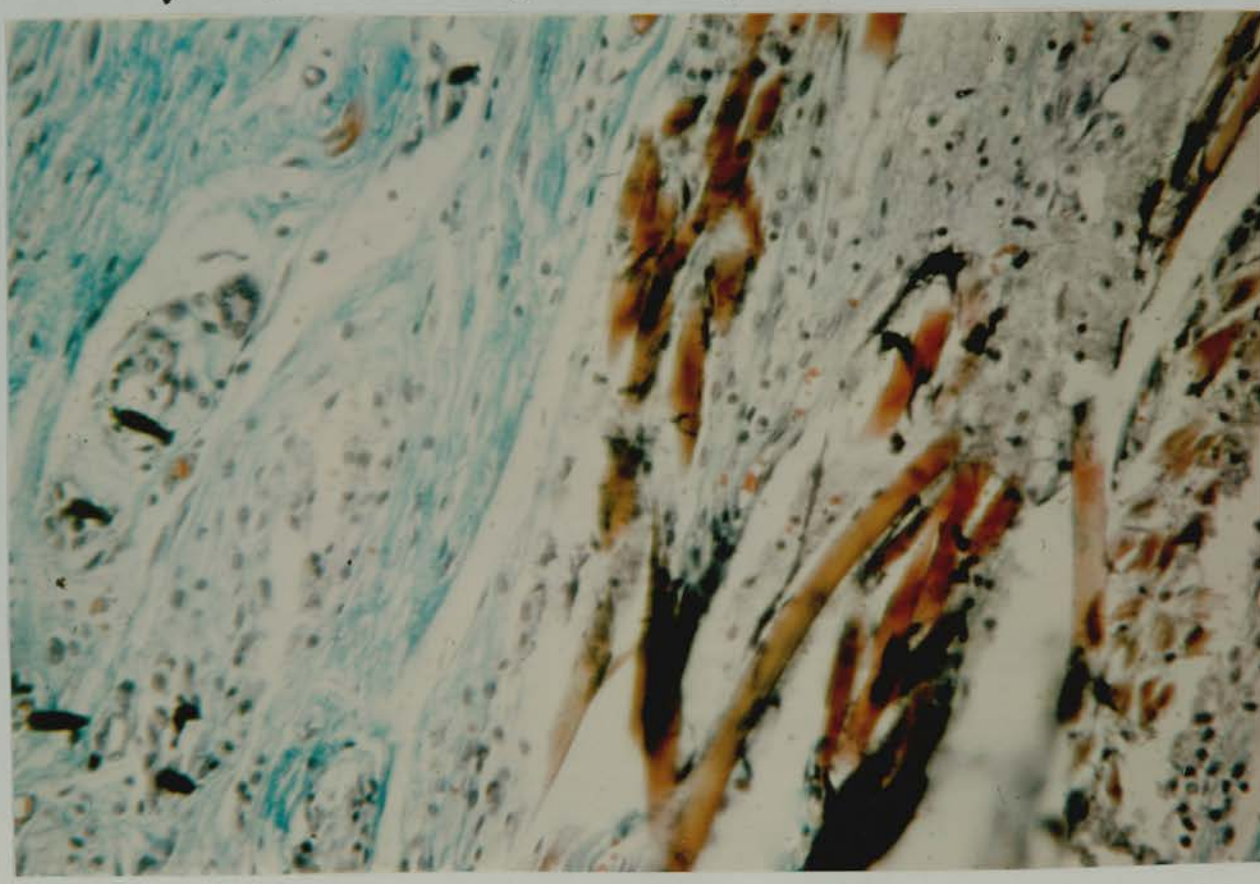


FIGURE 27A. Neo tendon induction in response to carbon (left of section) and a typical response to silk suture (right of section). The different response to the two materials is demonstrated. (x100 trichrome) nodes were disolved in boiling sodium hydroxide and filtered, the filter paper held small collections of black material which proved to be carbon. The conclusion was thus reached that the carbon fragments which had collected in the nodes were largely washed out during the preparation process, thus making the microscopic visulisation difficult. However, naked eye appearance of the whole node with its darkly stained periphery, in simple cross section showed a dark coloured material throughout the node, and the carbon filtered out following node disolution indicated that the material in the node was in fact carbon. This was finally confirmed by examination of adjacent tissue in which carbon was seen in the lymphatic ductules distal to the node under examination (Figure 30, Figure 31).

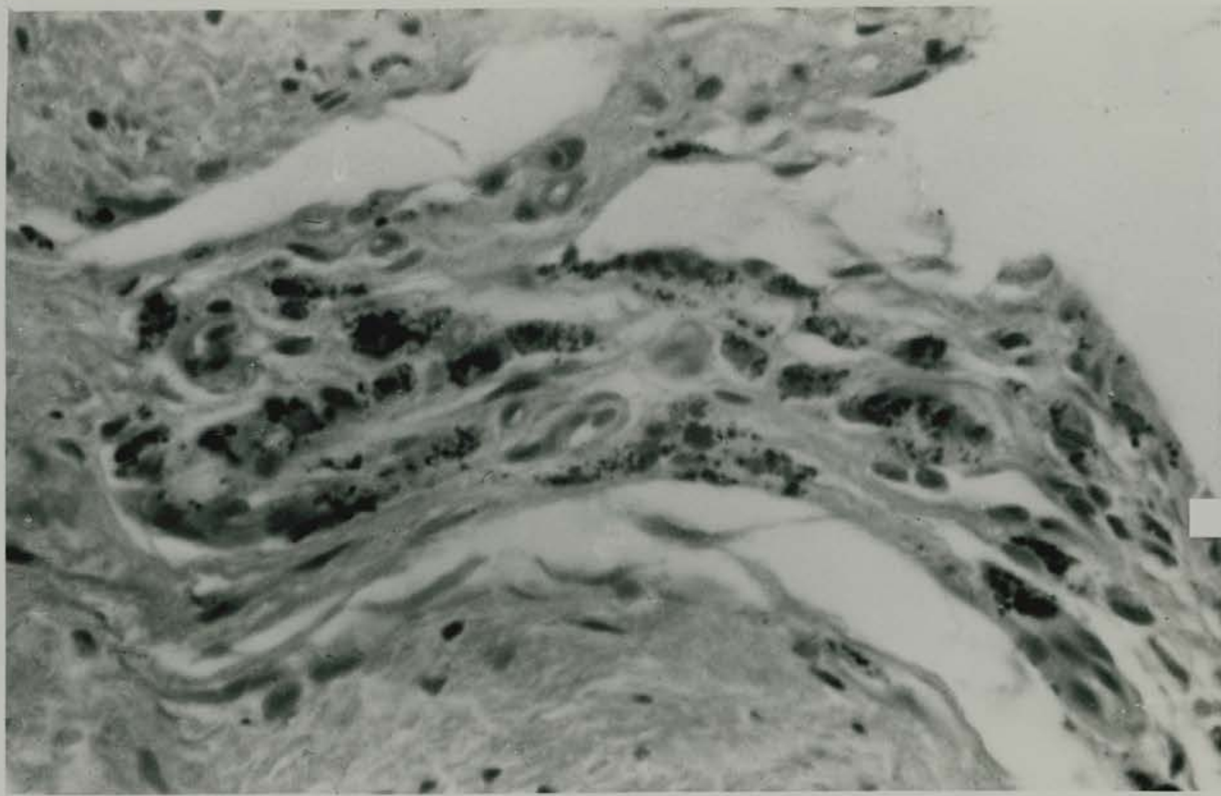
The implication drawn was that the carbon implant was fragmenting and following phagocytosis was to be found in the regional nodes.

Examination of the implants at one year and two years showed similar findings. Histological examination showed the individual filaments to be separated and in both groups also there was the same appearance of the implant side para aortic nodes suggesting that the breakdown of the carbon implant was continuing and that very gradually the regional nodes were receiving carbon fragments over a long period of time. (Figure 32).

Examination of surrounding tissues showed no evidence of any other change. Examination, both naked eye and histological, of spleen, lung, and liver, showed no evidence of any carbon fragments, nor was there any change from the normal appearance of these organs when compared with those of other non-implanted animals.

FIGURE 28. Para aortic lymph nodes. Carbon implantation side left and non implantation side right. X 10

FIGURE 29. Simple section of the para aortic nodes from the carbon implantation side at six months post implantation to demonstrate the heavy carbon infiltration. X 15



10μ H&E.

FIGURE 30.

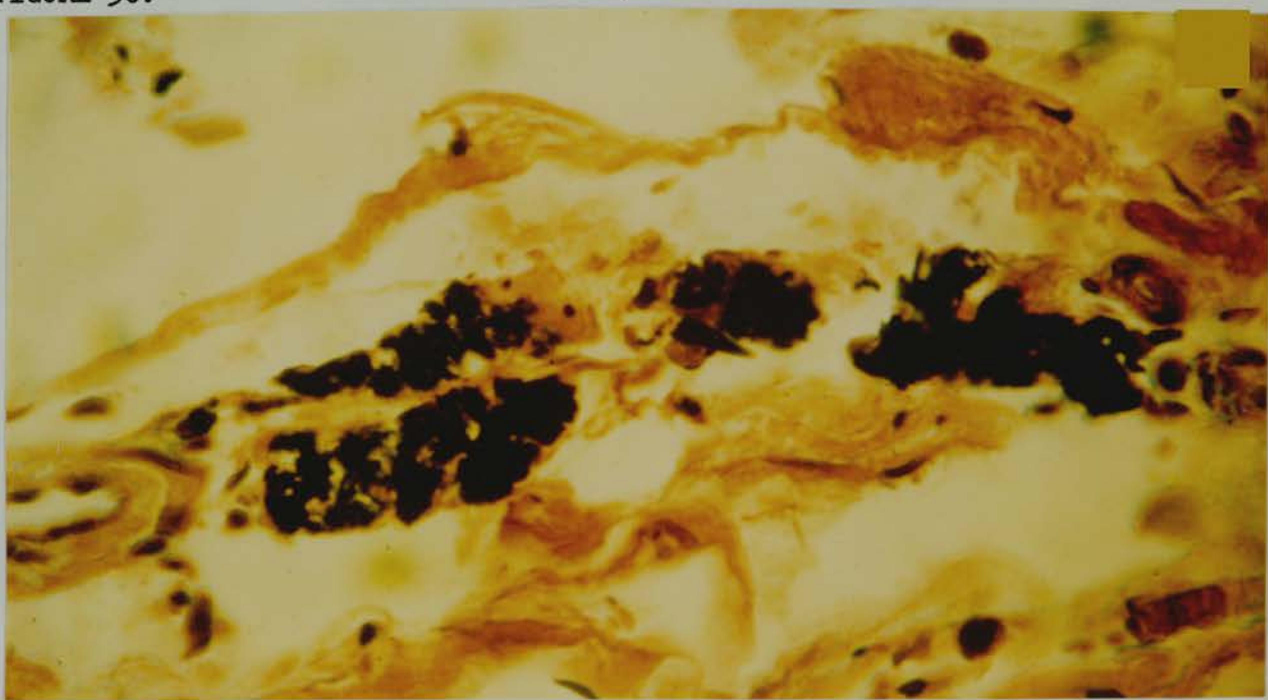


FIGURE 31. Sections from perilymphatic tissue proximal to the site of implantation of the carbon implant and just distal to the para aortic nodes on the implantation side to show heavy depostion of carbon fragments in lymphatic ductules.

10μ Van Geison

FIGURE 32. Disection of aorta, common iliac arteries and lymph nodes from sheep two years post carbon implantation. The implant was on the right side and heavy carbon deposition is seen on that side only.
(0·25 size.)

The inference was drawn that the presence of the carbon implant did no more that stimulate a new tendon to form around and throughout the implant. There was no suggestion that any adverse response was seen at the site of implantation and surrounding tissues or in organs distal to the implant. With the exception of large quantities of carbon in the regional lymph nodes from the implantation side which appeared to cause the animal no disadvantage, there was no evidence of an adverse response in any other organ of the reticulo-endothelial system, or in any other organ of the body. Thus it was concluded that the carbon implant was safe for further human use.

(b) CONTROLS

1. Nylon - None of the nylon control sheep were able to bear weight on the operative side at any time up to their time of sacrifice at six weeks. At this time, they were put down since it was considered unreasonable to let them live longer. Naked eye examination showed that there was a thin band of fibrous scar tissue which, when histologically examined, proved to be connective tissue similar in type but markedly less in bulk than the carbon implanted specimen.

Furthermore, the nylon had cut free in two and in all the fibrous band was between one and a half and twice the length of the excised tendo-achilles. An expressed macrophage foreign body gian cell reaction was seen in all.

2. Silk - Similar features were seen in the silk controls. (Figures 33 and 34). The bulk of the new collagen growth was greater than that in the nylon group but far less than that in the carbon group.

FIGURE 33. Carbon fibre tow tendo achilles replacement in sheep one month post implantation into the sheeps left hind limb. The animal can bear weight and stands normally.

FIGURE 34. Silk implantation in the place of the tendo achilles on the left side in sheep one month after implantation. Total collapse of the calf muscle-tendon-complex is seen.

A florid giant cell response was observed and in all the band of new tissue was thin. Animals were not bearing weight though post mortem tests showed the silk to be intact. It was clear that any weight bearing propensity the animals might have had was due to the intact presence of the silk and not due to new tendon development. Thus the silk had acted in a manner of a true tendon prosthesis in which the silk had only replaced the tendon.

3. Polyglycolic Acid - None of the animals in the polyglycolic acid group were able to bear weight. All were put down by six weeks. Naked eye examination at six weeks showed collapse of the polyglycolic acid strands with development of flimsy scar tissue along the site of implantation. The naked eye and histological appearances were not dissimilar to those seen in the nylon group, and it was concluded that although polyglycolic acid has advantage in its removal from the site of implantation by digestion, it has no place in tendon replacement, because it fails to support the appropriate structures and does not induce new collagen formation.

4. No Replacement - Macroscopically, the appearances were similar to the nylon and polyglycolic acid group in that no animals were able to weight bear on the operative side. All were killed at six weeks. Histologically, there was a thin elongated band of fibrous tissue between the musculo-tendinous junction and the os calsis which was of much greater length than the originally excised tendo achilles, and was composed of a scanty fibrous connective tissue with little strength and clearly unable to support the weight of the animal.

The inference from this series of experiments was that the flexible carbon implant differed in behaviour and induced a remarkably different response in the animal to replacements with nylon, silk, polyglycolic acid and no replacement at all. The main features are that it promotes a florid fibrous reaction which leads to the development of a neo tendon with little evidence of a foreign body response. Thus it may be regarded as inert in the conventional terminology of biological inertness. Its promotion of florid fibrous reaction suggests that its physical form may be responsible for this. It appears to actively induce new tendon to form which has the histological appearance and acquires the shape and properties of new tendon.

EXPERIMENT 8

Of the animals not killed for the purposes of histological examination at a relatively early stage, these were kept for long term observation on the behaviour of the carbon implant. The features seen at one and two years following implantation were similar. All long term surviving animals were able to function normally with no outward evidence of any detriment. Four ewes became pregnant and gave birth to normal lambs. To naked eye view the carbon implants removed after one year were firmly embedded in new tendon tissue which apart from slightly increased bulk, had the appearance of normal tendo achilles. Histologically, examination showed similar appearances as those seen at six months (Figure 35), but in addition, there was marked evidence of fragmentation with what appeared to be carbon dust in relation to the readily recognisable filamentous carbon fragments, widely dispersed in adjacent soft tissue. Thus it appeared that fragmentation was continuing towards a state where the smaller fragments were further breaking up into carbon particles (Figure 36). Examination of the regional lymph nodes showed them to be packed with carbon. This only occurred in the first main proximal groups of lymph nodes (the para aortic nodes on the side of the implant) and nowhere else. The nodes were larger than those on the opposite side and were seen to have a ring carbon around the periphery and when sectioned, were seen to be packed throughout with carbon particles. Similarly, the adjacent distal lymph tissue was found to be packed with carbon particles.

The inference was drawn that regional nodes were acting in an established manner to any particulate foreign body, namely that of filtering and holding the carbon particles without further proximal spread.

The experiments described suggest that filamentous carbon fibre is accepted in living tissues with virtually no adverse reaction. It appears that the filamentous implants ~~that~~ have the power of attracting connective tissue ingrowth within their interstices with the laying down of substantial deposits of strong collagenous fibres. When placed in a functional position and subjected to forces predominently in one direction, these collagen fibres appear to have gradually orientated themselves in one direction so that, after eight to twelve weeks, a structure very closely resembling a natural tendon or ligament results. In the plaited form, it appears that the original carbon fibre may disintegrate having outlived its useful period and thus acted as a temporary scaffold into which new tissue can grow. The rapid development of the new collagenous tissue suggests that this has been induced, in part at least, by the presence of the carbon.

FIGURE 35. Fragmentation of carbon fibre implant and separation of the individual filaments at the periphery following implantation at one year. The more densely packed carbon fragments are seen in the more central part of the neotendon (top right) x40 Van Geison.

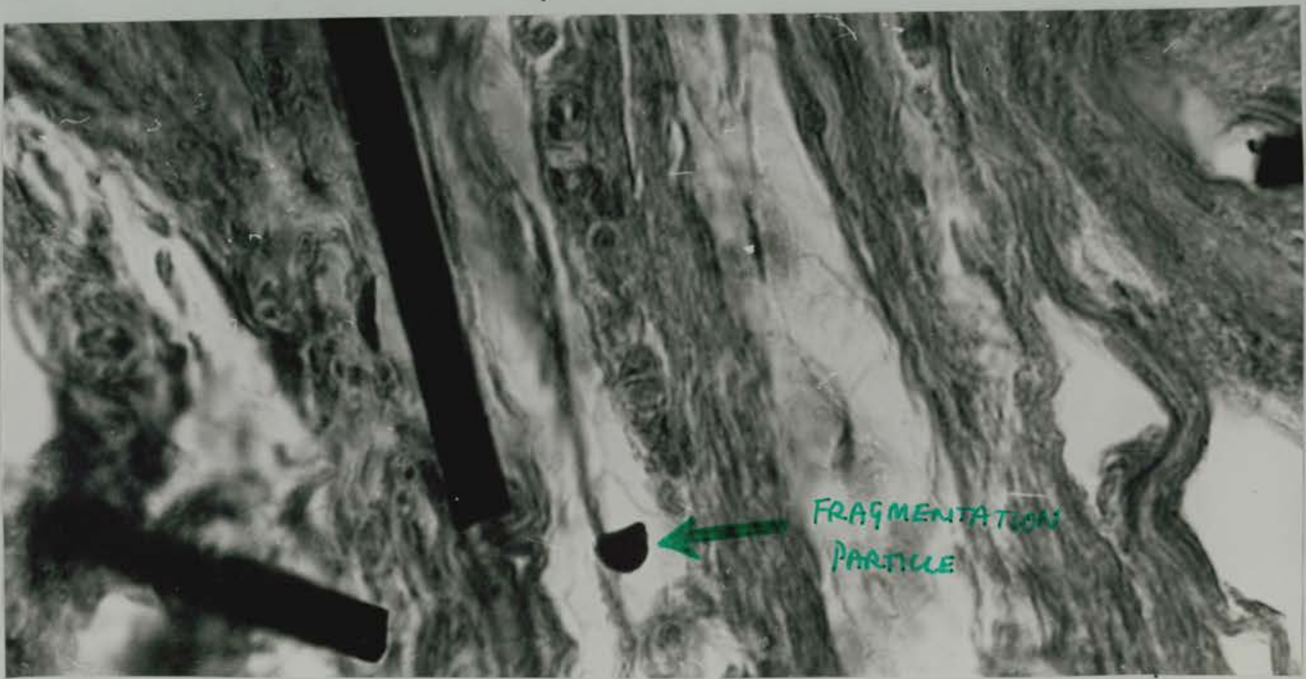


FIGURE 36. High power view of section of neo tendon showing fragmentation of carbon.

10µ. H&E.

One may speculate that the key to success is the gradual mechanical failure of the carbon that allows a gradually increasing load to fall on the newly forming collagen and so encourages the fibroblasts to become orientated in the direction of stress.

It certainly appears that filamentous carbon can be used to induce the formation of new tendon or ligament with a physical strength equal to that of the normal structure. This phenomenon has obvious clinical significance. Clearly, since the formation of the new structure is dependent on the extensive invasion of connective tissue, its use as a ligament is restricted to those sites where adhesion formation is of little consequence. Trevor (1950) drew attention to the fact that a thin band of tissue grew along the line of the original tendon when the divided ends of the tendon were not approximated. In our control animals in which the tendon was not replaced, a similarly poorly developed band was seen. Trevor's use of nylon as a bridging material encouraged us to use this material in our second control group and we also found a thin poorly developed band of tissue along the line of the nylon.

The effect of the carbon implants was different in three respects.

Firstly, a new tendon of size and strength similar to that of the normal side developed. Secondly, no sinuses formed, thirdly, the histological evidence suggested that the new tendon was actually induced by the presence of the carbon.

It is in this last respect that filamentous carbon differs fundamentally from all other forms of tendon replacement materials. Although some success has been achieved using materials such as silk (Heinze and Mayer 1914), Teflon (Williams 1960), Silastic (Bader and Curtin 1968), and Silastic with Dacron (Salisbury, Mason, Lebine, Pruit and Wade 1974) all of these have been used simply to replace tendons. Filamentous carbon is only similar to these materials in the first few weeks after implantation. Thereafter, the newly induced tendon takes over the action of the implant and the implant itself becomes progressively more irrelevant to normal function. The partial disintegration observed in some animals indicates that the implant has outlived its usefulness and has truly acted as a temporary scaffold while new tendon develops. Thus there is no need to consider the time over which such an implant will last before mechanical breakdown occurs.

EXPERIMENT 9

In order to determine whether the new tissue growth into the interstices of the carbon was a feature of the fibrous connective tissue only, the os calcis from the animals used in earlier experiments were excised and examined together with the new tendo achilles.

Initial experiments were conducted in which an attempt was made to pull the carbon free from the hole in the bone into which it had been led at an earlier time. This was achieved by disection of all new connective tissue from the edges of the carbon matrix but it was, of course, impossible to remove connective tissue which had grown into the carbon itself. That it was not possible to pull the carbon free at any later period than six weeks, indicated good fixation to bone. The nature of the bony fixation was seen by histological examination of decalcified bone sections. At periods from six weeks to four months, the fibrous tissue previously observed around and within the carbon matrix was also seen within the carbon inside bone. Thereafter, new bone growth was clearly seen with new bone also forming within the carbon matrix. It was thus concluded that while bone ingrowth was slower than fibrous tissue response, new bone growth had actually occurred, thus firmly anchoring the carbon in its implantation site.

EXPERIMENT 10

In four sheep the medial collateral ligaments and capsule of the knee were excised in such a manner that there was no medial support to the knee and following excision valgus strain of 40° was easily achieved. The medial aspect of the knee was supported by a double plaited strand of filamentous carbon passed through suitably placed holes in the distal femur and proximal tibia, fixed by knotting and supported on the lateral sides with stout silk sutures, The knee was held at 30° flexion during final tying of the flexible carbon plaits and when fully extended was seen to be tight, but not restricting. Since the sheep knee is rarely fully extended, except when running, the primary aim was to restore stability at approximately 25° flexion. Figure 36.

In four control animals the medial collateral ligaments and capsule were excised and no support was provided.

No postoperative immobilisation was used.

Sheep in the carbon reinforced group were able to walk without apparent discomfort on four legs within one week (Figure 37). Lateral varus strain at one month and later at six months, showed no evidence of instability. A full range of movement including full extension was readily achieved, (Figures 38 and 39). In the control group at one month there was marked valgus instability but by six months, this instability had disappeared.

Histological examination of two sheep knees at two months showed there to be an apparent capsule consisting of fibrous tissue surrounding the implant but with little ingrowth. Where the carbon passed through the bone there was no bone ingrowth, instead, fibrous tissue had grown into the gap between carbon and bone and was responsible for the tight hold at this point. Six month's examination of the remaining pair of sheep showed similar findings to those seen in the tendo achilles.

New bone had formed within the intersteces of the outermost parts of the carbon implant where it passed through bone. Carbon filaments were separated and full ingrowth of fibrous tissue had occurred in the parts of the carbon implants surrounded by soft tissue.

Histological examination of the knees of the six month control animals showed heavy fibrous scarring on the medial aspect of the knee and this was interpreted as a normal repair process.

The implication drawn from this experiment was that, as in the case of the tendo achilles replacements, the implant of carbon was able to support the knee but that because of fibrous tissue ingrowth had been slower, the strain applied to the carbon had possibly been less than in the tendo achilles, thus the stimulation to fibrous tissue ingrowth had been less marked and hence the delay in ingrowth.

FIGURE 36.

Medial collateral ligament replacement

in the sheep knee

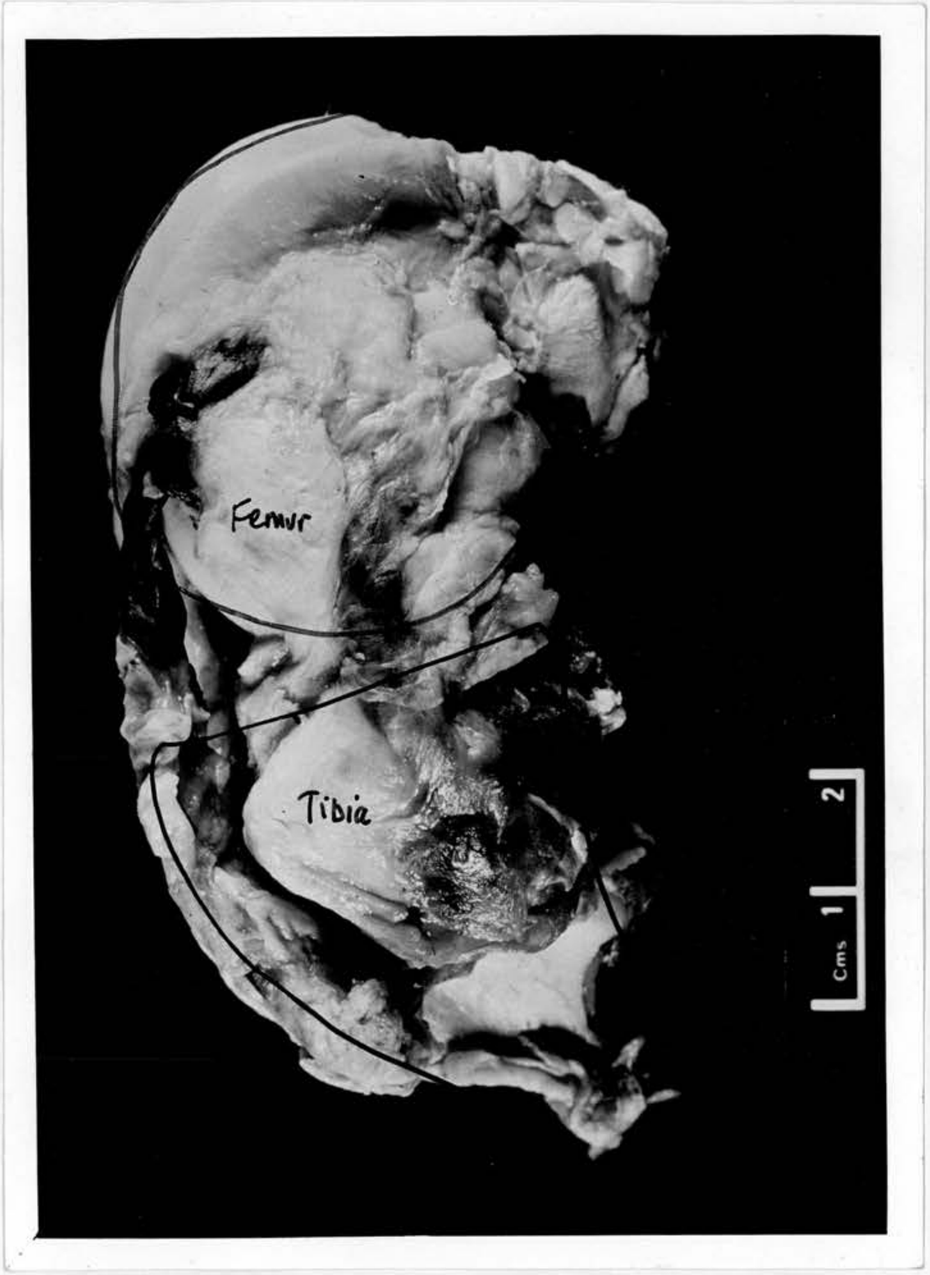


FIGURE 37. Appearance at one month in which gradual envelopment of the medial collateral replacements is demonstrated.

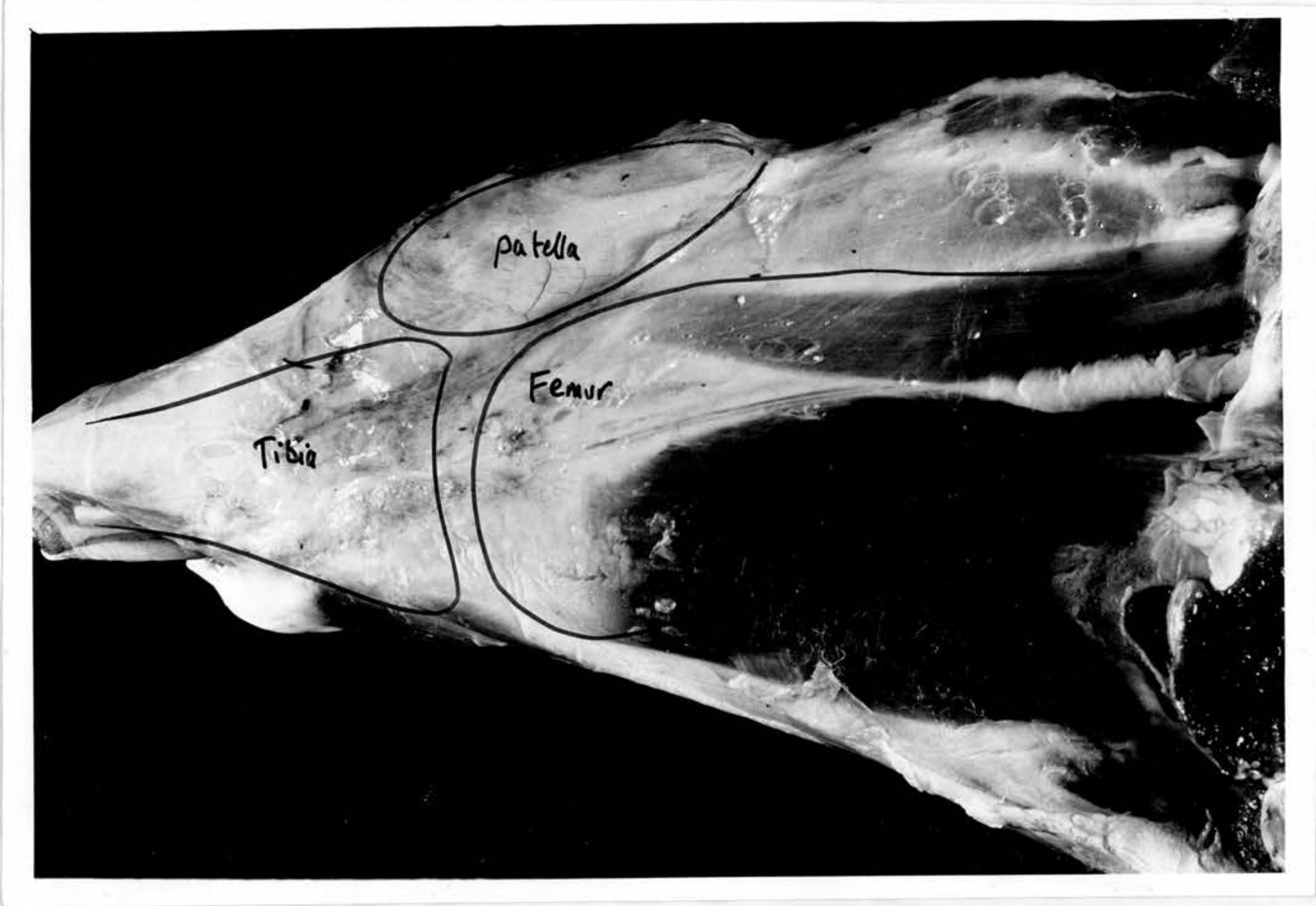


FIGURE 38 Sheepknee in full extension six months after replacement df the medial collateral ligaments.

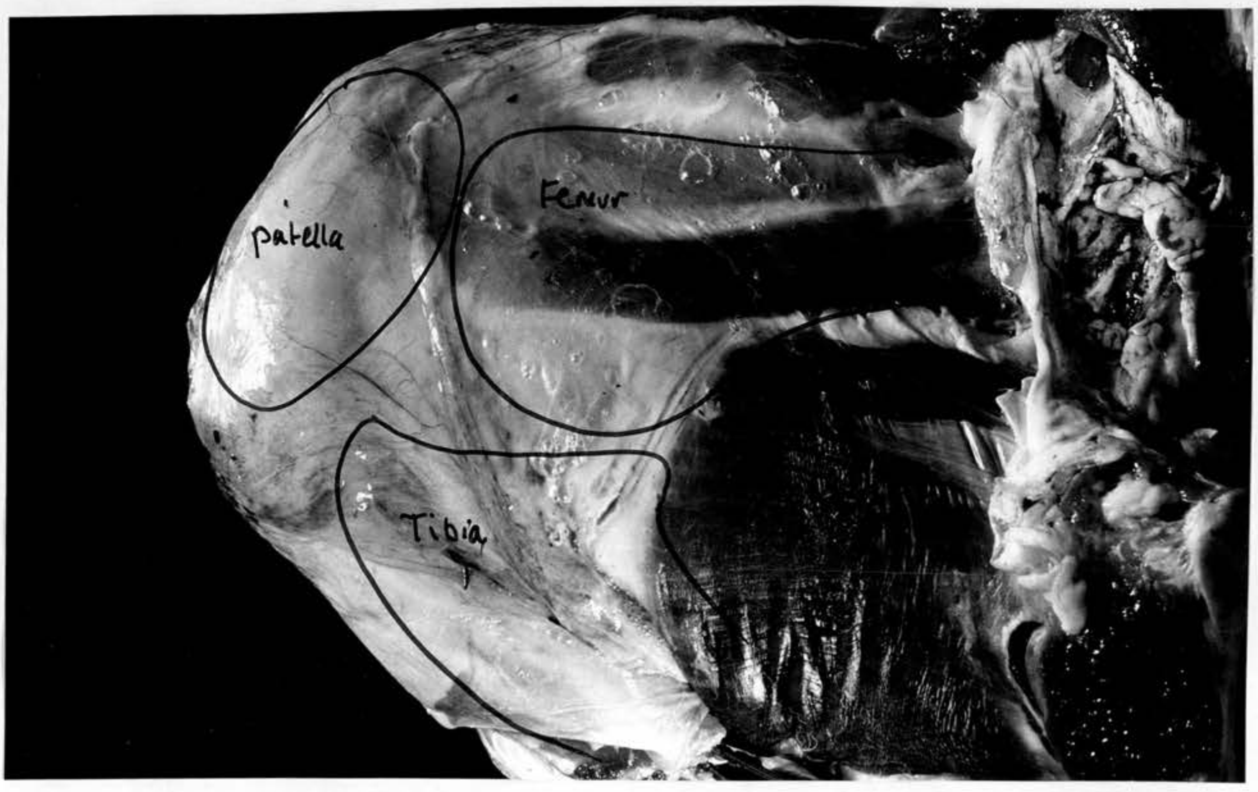


FIGURE 39. Sheep knee in full flexion six months following replacement of medial collateral ligaments.

EXPERIMENT 11

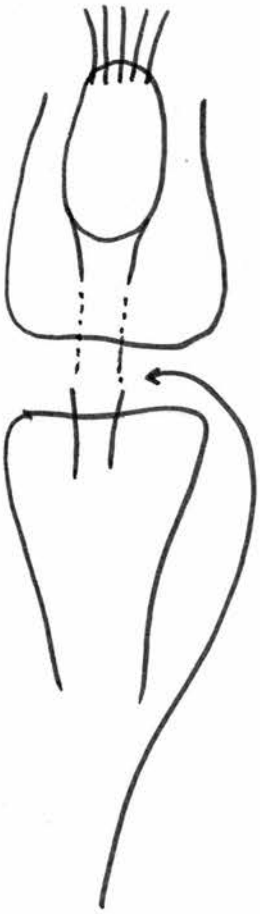
In two sheep the patella tendon was excised and two carbon plaits passed through the distal pole of the patella and through the tibial tuberosity. This experiment was performed primarily to determine whether the method of treatment was suitable for one human patient who presented a late rupture of the patella tendon. Both sheep were left unsupported as with other experiments.

The animals were able to bear weight at one week. At six-months there had been massive new growth of fibrous tissue in and around the carbon with firm bone fixation (Figure 40). The new patella tendon, similar in form and function had formed in the region of the implant.

EXPERIMENT 12

All experimental models described in the sheep lower limb had demonstrated that the ingrowth of new tendon had occurred not only from the proximal and distal ends of the implant, but also from the sides, and the question of actual site of new ingrowth, still remained. Earlier pilot experiments on the rabbit had suggested that ingrowth could occur from the ends alone, but that it was slower than when adjacent soft tissue was in close proximity with the carbon.

The only ligamentous structure in the body which is not in contact with other tissues is the cruciate ligaments. In six sheep the anterior cruciate was excised totally and replaced with a single plaited strand



incision in
patella tendon:
knee then
fully flexed
A.P. view.

FIGURE 40. Patella tendon replacement with carbon fibre. The replacement has been divided transversely to show the marked response to the implant.

of filamentous carbon. This was achieved by drilling suitably placed holes through the femur and tibia and passing the carbon from femur across the joint through to the tibia and then fastening in the correct degree of tension. Care was taken to ascertain that the knee had a full range of passive movements before closure.

Animals were killed at two and six months. At two months the carbon was readily visible to the naked eye but was covered with a fibrous capsule similar to that seen in the three month specimens of medial ligament knee replacement (Figure 41). At six months the carbon was hidden in a white fibrous mass which closely resembled the normal remaining posterior cruciate both in form, function and histological appearance (Figure 42). New bone growth had occurred within the site of the bony implanted area and was responsible for the strong hold of the carbon. In all knees, there was some limitation of movement with a loss of approximately 20° flexion in each.

The implication was drawn that the new tendon had formed along and throughout the carbon implant by growth from either end, thus demonstrating that lateral ingrowth was not a necessary factor in new tendon formation.

EXPERIMENT 13

In the previous experiment, a filamentous carbon strand with approximately the same bulk as the excised anterior cruciate had been used to replace the anterior cruciate and it was noted that the newly induced tendon was of considerably greater diameter than that which had been excised. It was felt that this was in part responsible for the slight

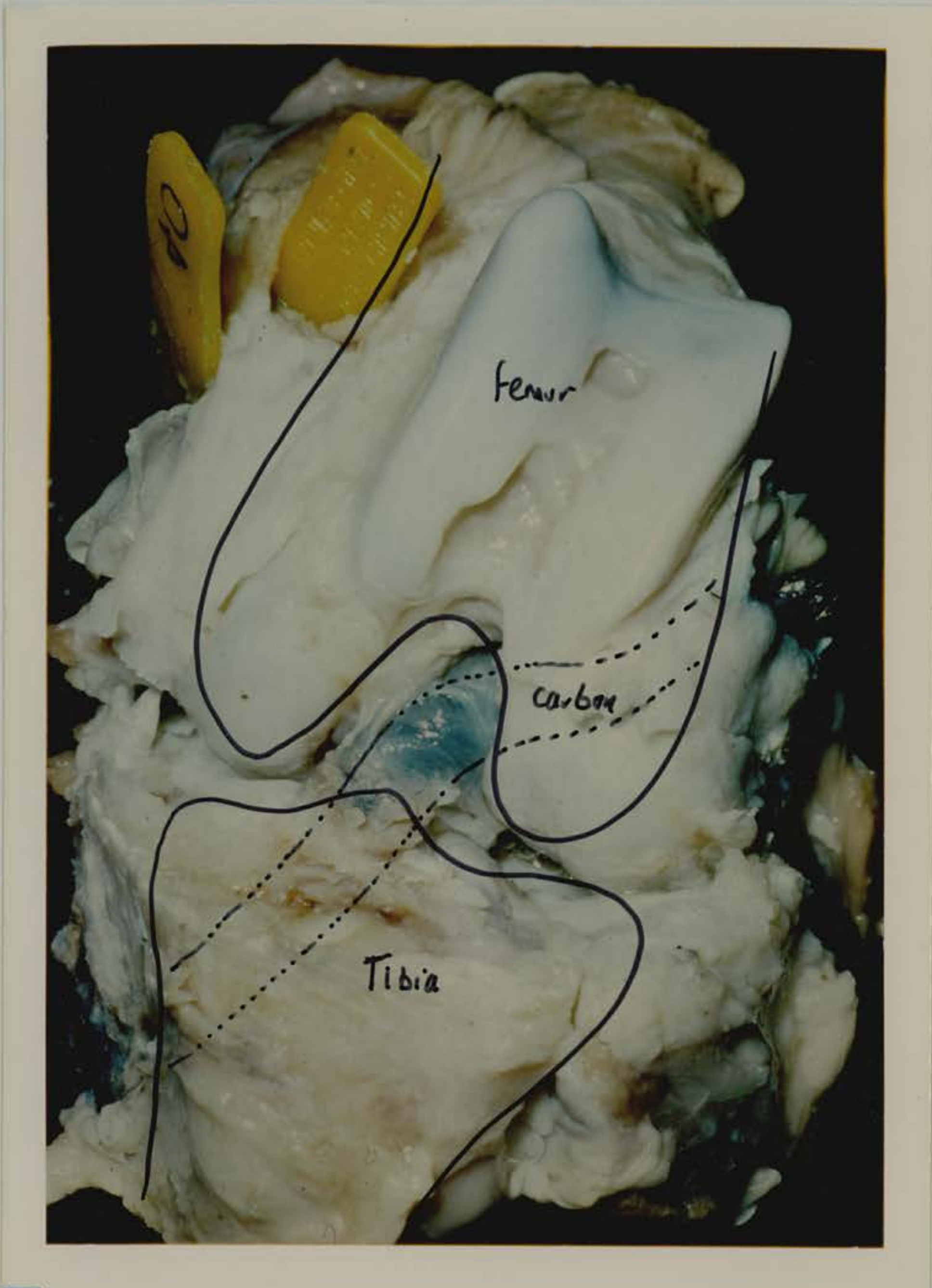


FIGURE 41. Appearance of the carbon fibre replaced cruciate ligament at two months post implantation.

1·0cm

FIGURE 42. Appearance of the carbon fibre replaced anterior cruciate ligament in the sheep at six months post implantation.

limitation of knee flexion seen in these animals.

In order to determine whether a new cruciate ligament could be induced to form from a markedly reduced number of individual carbon filaments, further experiments were performed.

Experiments were conducted in eighteen sheep.

In each of two groups the anterior cruciate was excised and replaced with filamentous carbon. In the first group of nine sheep, the anterior cruciate was replaced with a triple strand of carbon fibre containing approximately 13,000 individual filaments. The diameter of this strand of carbon was approximately similar to the excised anterior cruciate ligament. In the second group, the anterior cruciate was excised and replaced with a single strand of filamentous carbon, containing 3,000 individual filaments. Animals were put down at periods ranging from two months to six months.

RESULTS

In the sheep in which a thicker strand of filamentous carbon had been used, a bulky neo tendon developed. In the sheep in which the thin strand, approximately one quarter of the diameter of the normal cruciate ligament was replaced, a new tendon developed of approximately the same size as the original tendon. This feature was seen to be permanent in animals beyond six months post implantation. In the earlier experiments in which the tendo achilles had been replaced, the marked increase in volume in response to carbon had been noted and this experiment confirmed the property of carbon to induce a large volume tendon. As a practical guide to the possible use of flexible carbon in the human with an anterior cruciate tear, the implications are that the volume of carbon used should be approximately one quarter of the volume of the

tendon or ligament which it ~~was~~ is planned to induce (Figures 43 and 44).
45.46 and 47

EXPERIMENT 14

Because there was a satisfactory demonstration that new tendon would grow from the end and not necessarily from adjacent soft tissue, experiments were performed in which filamentous carbon was used to replace flexor tendons in hens and rabbits.

In four adult hens the common flexor tendon was excised from its musculo tendinous origin to a point 1cm proximal to its division into well defined individual parts. Thus, 5cm of tendon was excised and replaced with a suitably plaited flexible carbon replacement one half of the bulk of that used in the sheep experiments and similar in size to the excised tendon.

The carbon was threaded through the tendon remaining at both ends and supported with stout silk sutures.

All hens were able to stand on both legs by five days. Active flexion was observed for the next three weeks, but thereafter, there was no evidence of active flexion (Figure 48). Histological examination at four months showed that the implant was surrounded by a similar capsule to that seen in the medial ligament sheep knee experiments and that the implant was firmly bound down throughout its length to other soft tissue, and flexor tendon sheath. This confirmed the lateral ingrowth of tissue for flexor tendon replacement. There was some suggestion that the potential gap between the serous and parietal layers of the sheath was developing, (Figure 49)
and with this in mind further experiments were performed on rabbits in which the same tendon was replaced in hind limb on one side.

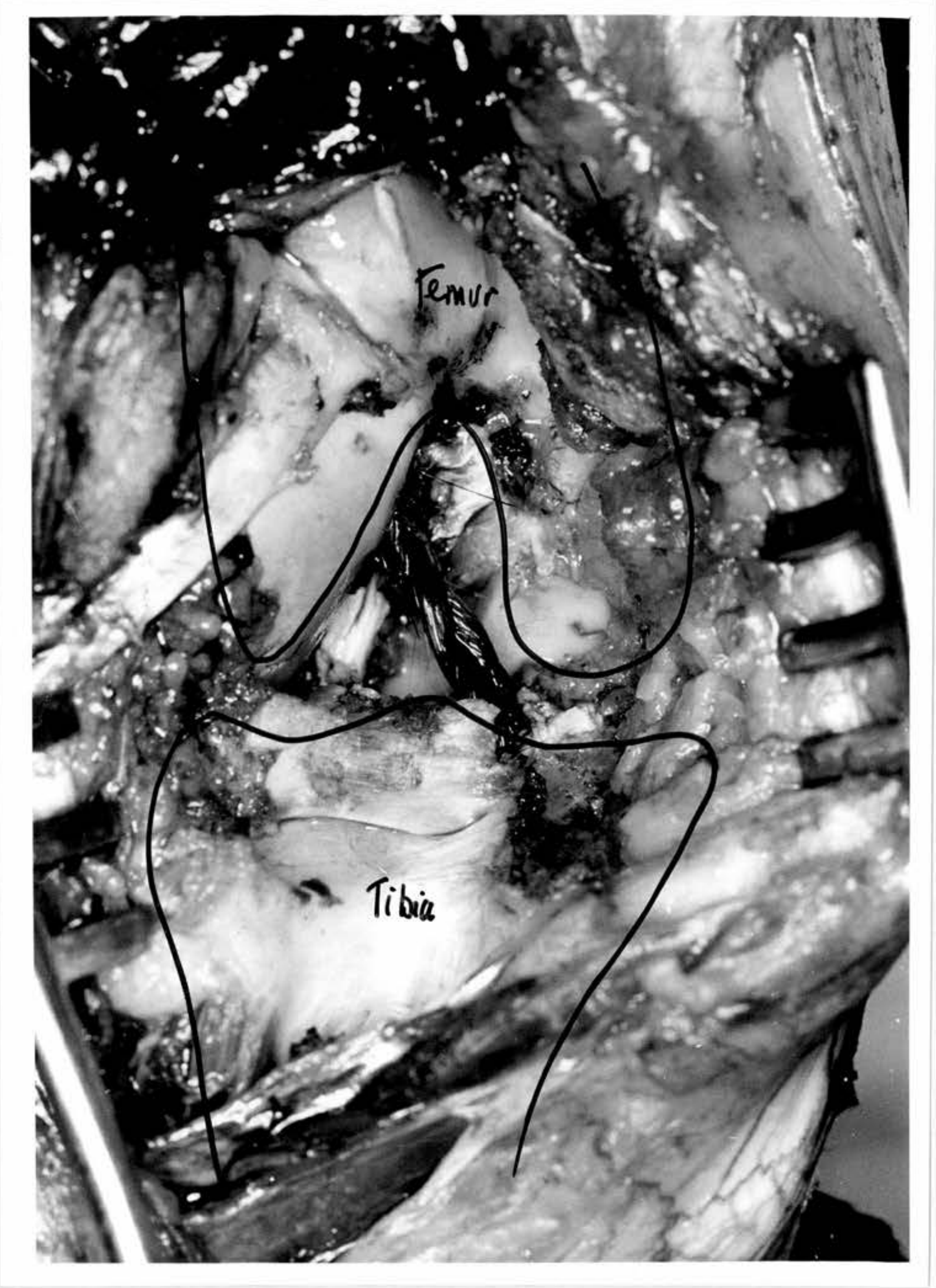


FIGURE 43. The anterior cruciate ligament has been replaced after total excision by a thick plaited strand of filamentous carbon fibre tow.

1·0 cm

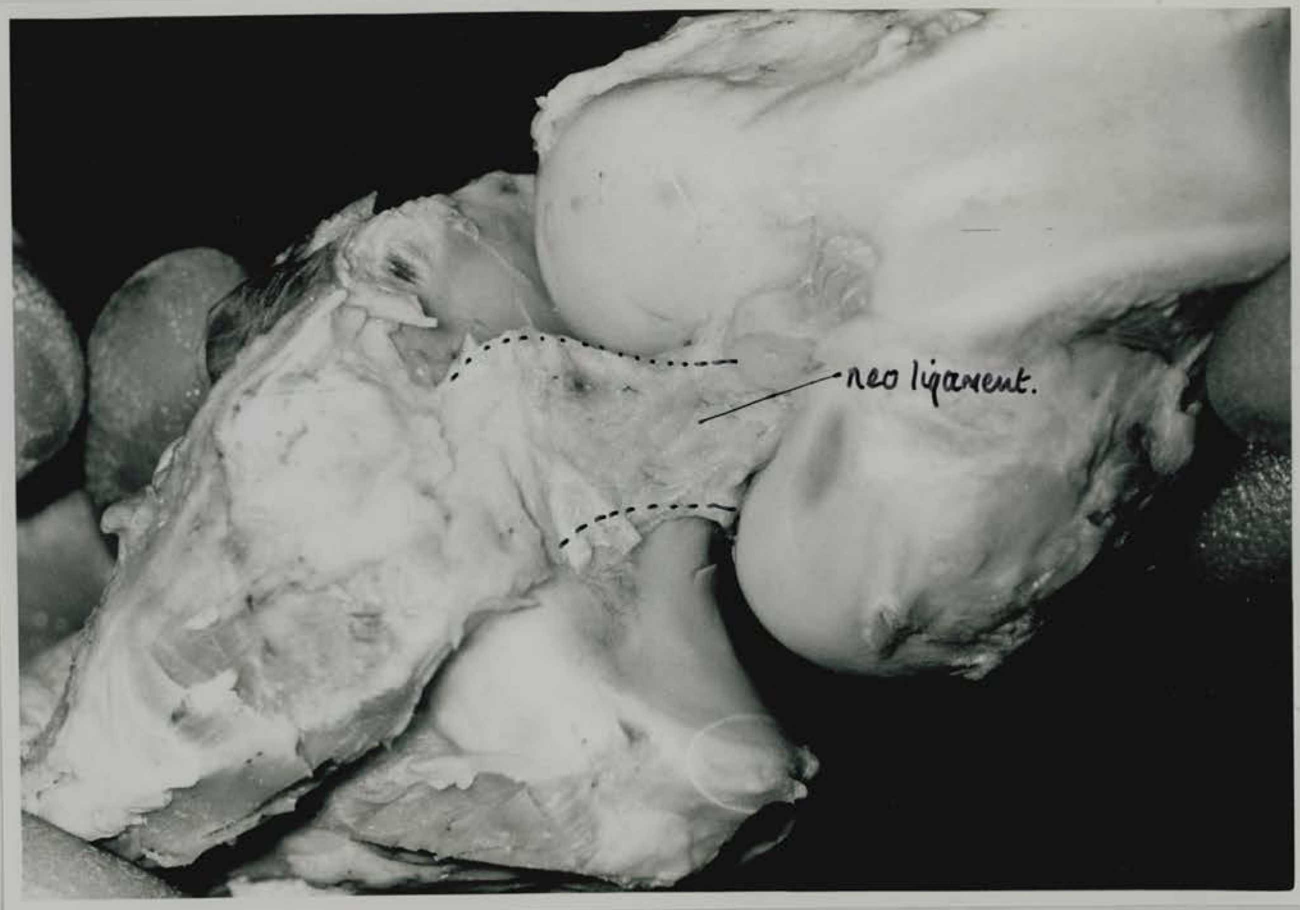


FIGURE 44. The appearance of the new cruciate ligament induced by the thicker plaited carbon fibre tow after three months. 1·0 cm

FIGURE 45. The macroscopic appearance of the new anterior cruciate ligament sectioned longitudinally three months following implantation

1·0 cm

FIGURE 46. The normal anterior cruciate ligament (deliniated by a single silk thread) in the knee of the sheep.

1·0 cm

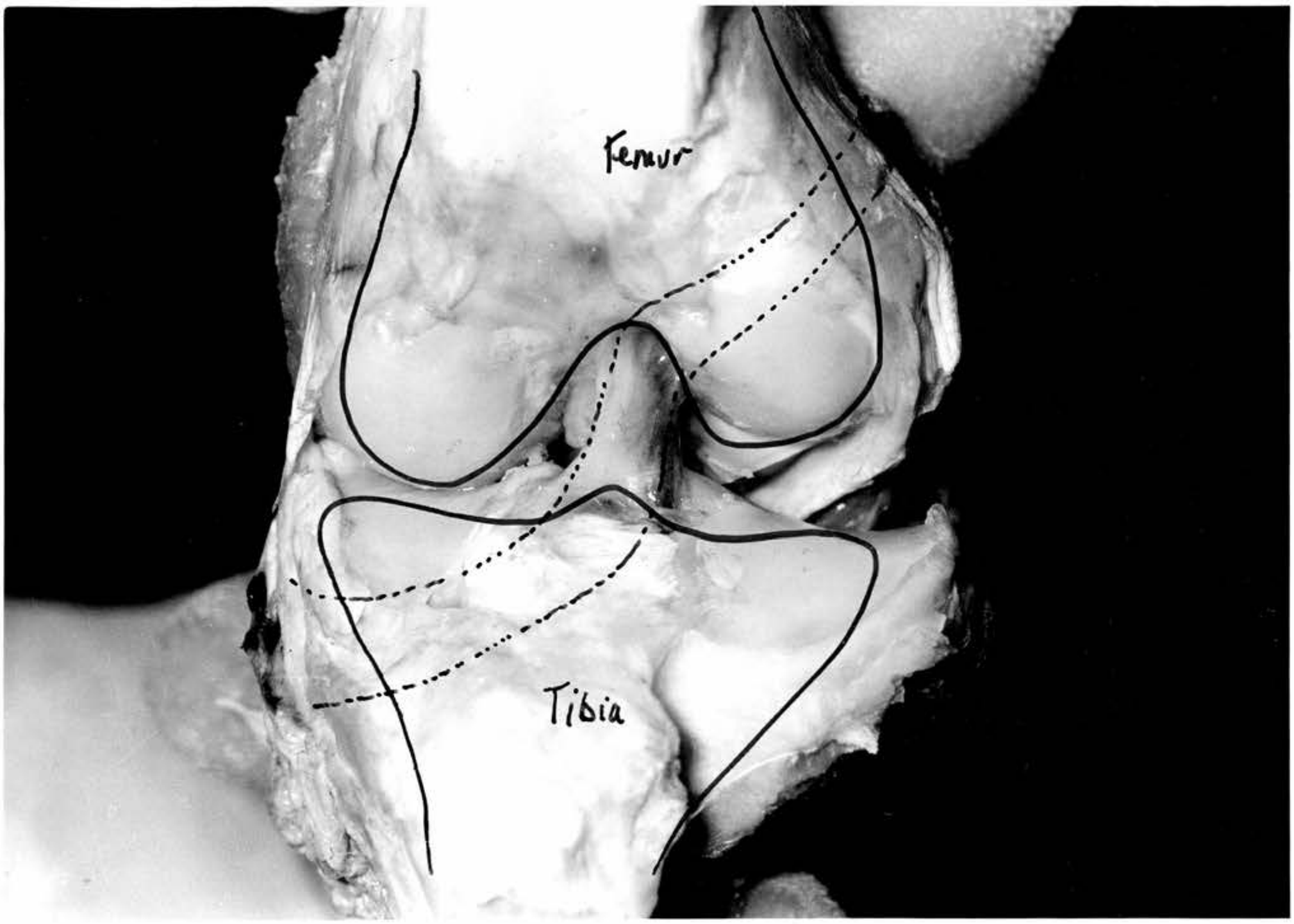


FIGURE 47. The appearance of the induced anterior cruciate in the knee of the sheep three months following implantation. Attention is drawn to the close similarity between this new ligament and that of the normal ligament in Figure 46. In this example the thinner strand of carbon was implanted.

1.0 cm

FIGURE 48. The common flexor tendon in an adult hen has been excised and replaced with filamentous flexible carbon fibre. Despite dissection to demonstrate the integrity of the carbon, adhesions at the distal end are clearly demonstrated. Specimen taken 2 months post implantation.

FIGURE 49. Histological section of the above at the distal end of the carbon showing separation of the carbon filaments and a possible separation between serous and parietal layers of the new sheath (arrowed).

(x40. H&E.)

EXPERIMENT 15

In four rabbits the long digital flexor tendon was identified and excised from its musculo tendinous junction to a point in the middle of the metatarsals. A single strand of filamentous carbon fibre containing approximately 3,000 individual units was used to replace the tendon. Care was taken to pass the tendon through the appropriate tunnels, thus mimicking, as closely as possible, the normal anatomy of the tendon it was replacing.

As with the chicken experiments, normal flexion was seen for the first month following implantation. At six months there was practically no active flexion, although at nine months there appeared to be slightly more flexion on stimulation.

Naked eye examination of the implant at dissection showed dense adhesions from the adjacent surrounding soft tissues, and this was confirmed histologically. The movement which had been seen to occur in the living animal, was in fact due to movement in the adherant soft tissue.

From these experiments, it was concluded that at this stage there is probably no place for the use of flexible filamentous carbon in flexor tendon replacement in the human.

However, it is possible that where soft tissue is loosely adherant to adjacent tendons, as in the case of the human extensor tendons on the dorsum of the hand, that despite adjacent soft tissue adherance, filamentous carbon might have a place in replacement of these tendons. One such example would be in the case of severe rheumatoid disease with associated tendon collapse in the hand extensor tendons.

Biological Reaction to Carbon Fibre Implants and the Formation and Structure of the Carbon Induced Neo-tendon

The generation of new voluminous fibrous tissue, the functional organisation of neotendon tissue with low toxic and little inflammatory reaction, together with the simultaneous removal of carbon, suggested that the presence of the carbon was in fact acting as a true tendon inducing agent. In order to understand the basic circumstances of this specific process, the following questions were asked:

1. What are the typical stages and time sequence of this bio-dynamic process involving the host's cellular reaction, production and organisation of new fibrous tissue and disintergration and removal of the implanted carbon filaments?

2. Is the production of functioning neotendons specific for carbon fibres, or can it be seen to a less degree using other materials?

3. What is the source of the newly induced tendon?

Further experiments on rabbits

In the first group, the Achilles tendon was replaced by a single loop of twisted carbon fibre.

In the second group, the Achilles tendon was excised and replaced by carbon fibre but was followed by dissection and excision of the posterior tibial nerve from the neurovascular bundle which lies close to the excised tendon.

In the third group, tendon was excised and not replaced.

In the fourth group, tendon was excised and replaced with silk in the manner described in earlier experiments.

In the fifth group, tendon was excised and replaced by nylon as described in earlier experiments.

All groups were sacrificed at periods between two weeks and six months.

RESULTS

Carbon induction of the new tendon (neo tendon) was shown to occur in phases. Histological examination of specimens suggested that three distinct and different types of tissue response could be identified in separate zones around and within the filamentous implant. The development of the different tissue response to the carbon was related to time.

In the initial stage, individual carbon filaments were seen to be closely packed together as in the original implant. The host tissue however, had started to penetrate from the outside amongst the closely packed filaments of the implant. Each of the carbon filaments had become coated along its whole length by a thin layer of macrophages and occasional foreign body cells, the nuclei of which were often arranged in an epithelioid fashion. (Figure 50). Young fibroblasts were seen in small numbers. The erosion process of the implant could be clearly seen at this stage, and was indicated by small intracellular chips of carbon debris and dust found around the individual carbon filaments.

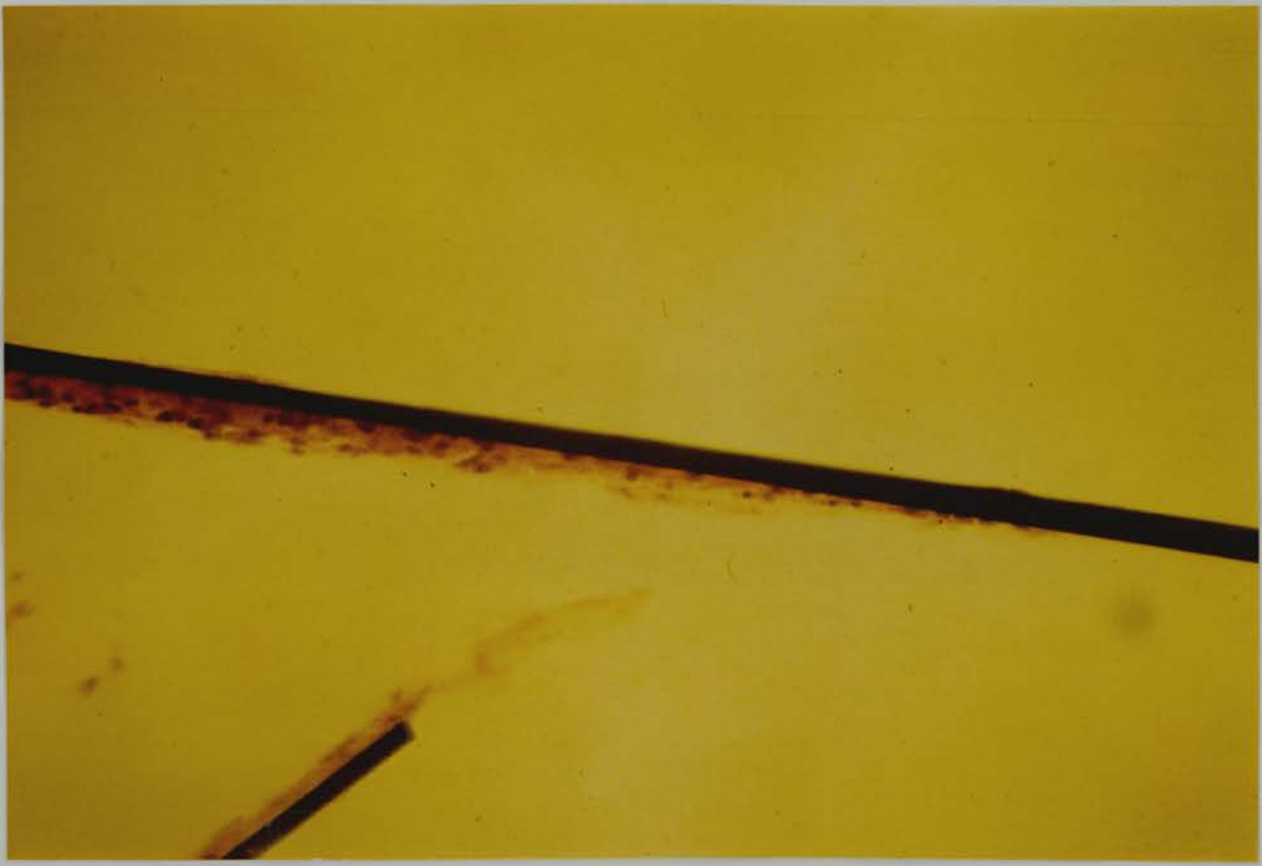


FIGURE 50. At two weeks post implantation each individual carbon filament has become coated with macrophages and young fibroblasts.

10μ

FIGURE 51. At four weeks post implantation young fibroblasts have aligned themselves along the individual filaments with subsequent collagen production. The apparent separation of tissue from carbon has occurred because of the sectioning process.

10μ

In the second stage, individual carbon fibres were still coated by the cells which characterised the coating tissue seen in the first stage referred to above, but were now separated by young granulation tissue invading from the outside and containing numerous capillaries, macrophages, mononuclear cells and less numerous foreign body giant cells, and also by streams of young fibroblastic tissue still producing larger amounts of young collagen on the periphery. (Figure 51). Small particles of carbon debris lying free were now less obvious and could be more often found inside mobile macrophages and foreign body giant cells.

In the third stage, fibro-tendinous tissues formed. Individual carbon fibres (each being coated by one single multinucleated cell only) lay far apart at a considerable distance from each other, being separated by a large amount of young and mature collagenous fibrous tissue which represented most of the specimen. (Figures 52 and 53). A possible source of this tissue is the loose mesenchymal material from the thickened perineurium and from vascular adventitia in the adjacent neurovascular bundle lying close to the implant. During the experimental period of up to sixteen weeks, the total amount of fibrous tissue gradually increased, and in the end exceeded the volume of the original carbon implant by as much as ten times in some cases. Over a period of time, this tissue had also changed its internal structure from less organised fibrous tissue through well formed groups of collagen bundles running parallel to the long axis of the neotendon up to a general architecture which is similar in structure to mature tendon (Figure 54). The continuous erosion and resorption of carbon filament is indicated by their gradually diminishing size and by the findings of carbon debris in mobile macrophages, distant lymphatic capillaries in muscle and later in the regional lymph nodes.

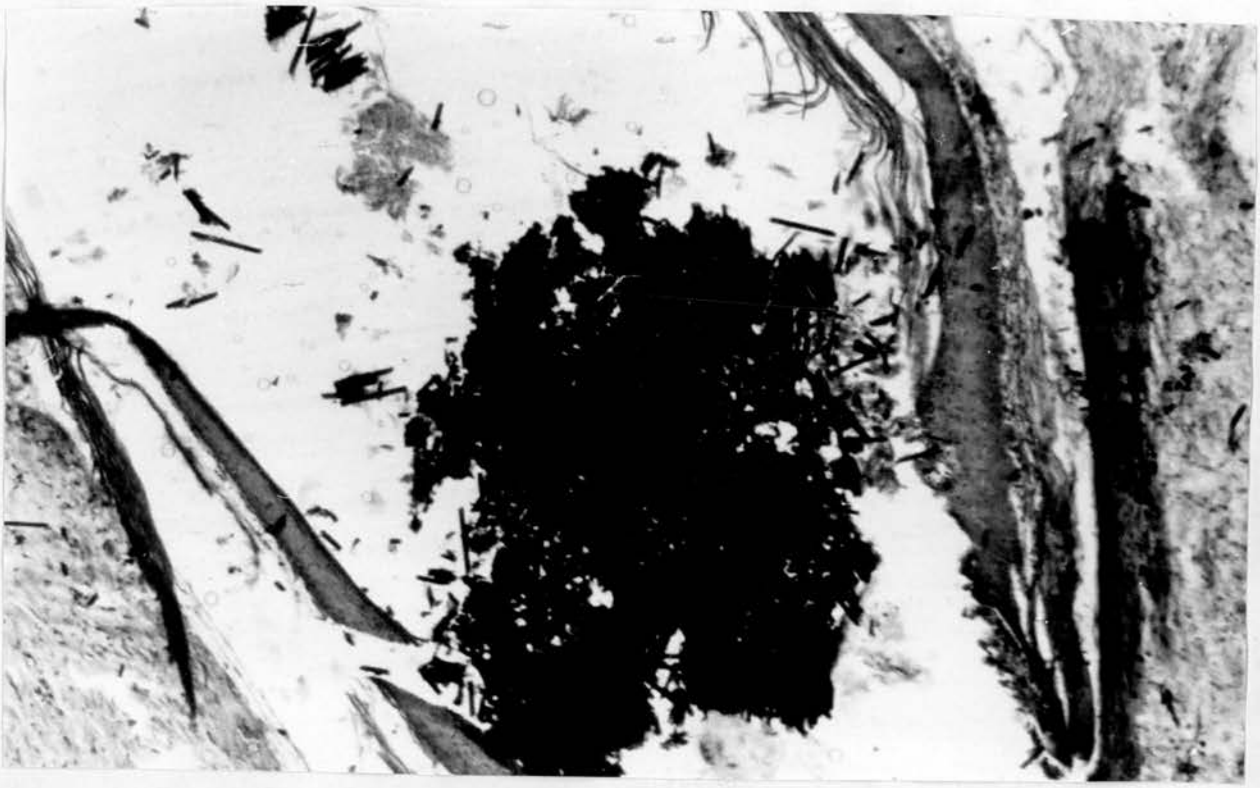


FIGURE 52. The initial cross section appearance of the tendo achilles implant in rabbits at two weeks. Apart from some early ingrowth at the periphery, the mass of carbon filaments remains as an intact bundle. (x25 H&E)

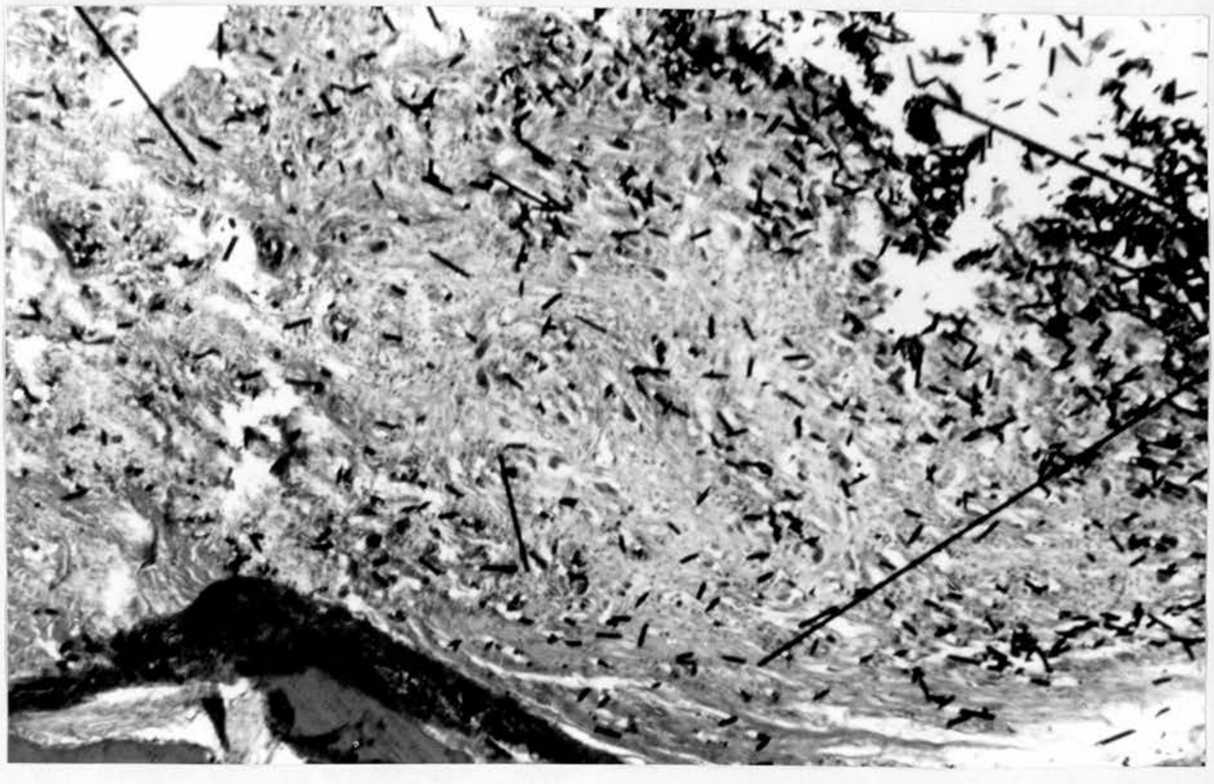


FIGURE 53. The appearance at two months demonstrating separation of the carbon filaments which is most marked at the periphery. (x25 H&E)

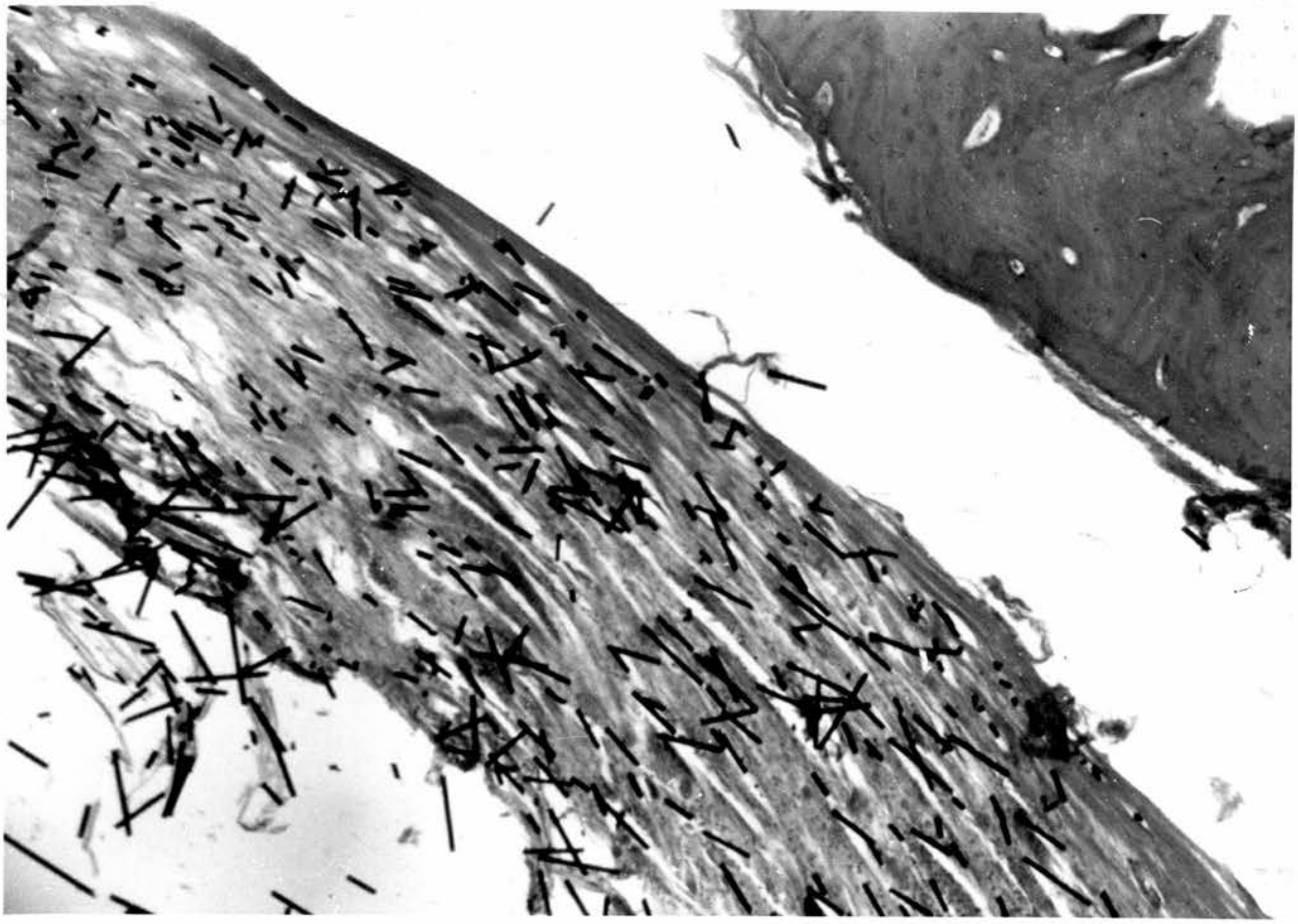


FIGURE 54. Longitudinal section of the induced tendo achilles in the rabbit at three months, showing wider separation of the filaments and production of a neo tendon throughout the implant. (x40 Van Geison)

In the denervated group, the overall volume of fibrous tissue produced was greatly reduced and it appeared that after the nerve with its perineurium was removed, the perivascular adventitial and local mesenchymal tissue became the main supplier of the fibroblastic material, although less successfully. Fragmentation and continuous resorption of carbon filaments, however, were undisturbed.

In this respect, the findings might be considered to be not dissimlar from comparisons made between the replacement of tendo achilles and the replacement of the anterior cruciate. In the former, perineurium and perivascular tissues were present, whereas, in the latter, no such elements are present and the new tendon development is correspondingly slower.

PRACTICAL USE OF FILAMENTOUS CARBON FIBRE

IN SURGICAL SITUATIONS

VETERINARY USES

Horse Fetlocks

The problem of stretched fetlocks in horses and the present unsatisfactory treatment of this condition with methods such as pin firing, has led to interest by several veterinary centres, in the possible use of filamentous carbon to reinforce the damaged fetlock suspensory ligaments. With this in mind, a pilot experiment was arranged with Mr. Hugh Littlewood, Veterinary Surgeon of Chipping Norton in a disabled race horse. The suspensory ligaments concerned correspond to the palmar-facia in the human, but in view of the lesser number of metacarpals, their greater length and different position and function, the suspensory ligament is a much larger structure.

Under general anaesthesia, the fetlock was exposed by a longitudinal incision over the distal part of the forelimb of the horse, and a double strand of prepared filamentous carbon fibre was woven backwards and forewards throughout the length of the fetlock in such a way that the length of the stretched ligament was reduced by 1.5 cms and was supported by the interlaced carbon. Following reversal of anaesthesia, the horse walked immediately and gradually regained its normal walking pattern over the following three months.

From this single pilot experiment, Dr. Alan Goodship of the School of Veterinary Surgery at the University of Bristol, in association with the author, decided to include the use of filamentous carbon in his experimental treatment programme of this condition which is supported by the Horseracing and Betting Levy Board. At this time, five such horses, have been treated in the manner described, and walking patterns are being examined on a gait analysis machine.

It is premature to comment on the results at this early stage, except to say that the early results compared very favourably with other established techniques of treatment of this particular condition. One formerly disabled race horse has now returned to training (Figure 55).

Hernia Repair

In view of the intense fibrosis initially induced by the presence of filamentous carbon and the subsequent alignment of fibroblasts and collagen, a short pilot experiment is in progress in order to examine the possible use of this material in ventral hernia repair.

In each of four groups of five sheep, ventral hernias were created by excising the majority of the anterior abdominal wall muscles, but with preservation of normal skin cover. (Figure 56).

Hernias were repaired by the use of mersaline mesh, interwoven Dexon (polyglycolic acid) fibres, interwoven individual nylon strands and interwoven filamentous carbon. (Figure 57). A control group in which no repair was attempted was also prepared.

In the control (no repair) group, all sheep developed massive ventral hernias and later required subsequent repair. The polyglycolic acid group and the nylon group, also developed ventral hernias, and examination

FIGURE 55. The first horse in a series of five treated with filamentous carbon fibre in support of the suspensory ligaments of the distal forelimb. (Right side).
The gait is normal and weight is borne on the affected forelimb without collapse of the radiocarpal or carpometacarpal joints.

FIGURE 56. Preparation of a large ventral hernia in the abdomen of the sheep by excision of the muscles of the anterior abdominal wall. The peritoneum and skin remain intact.

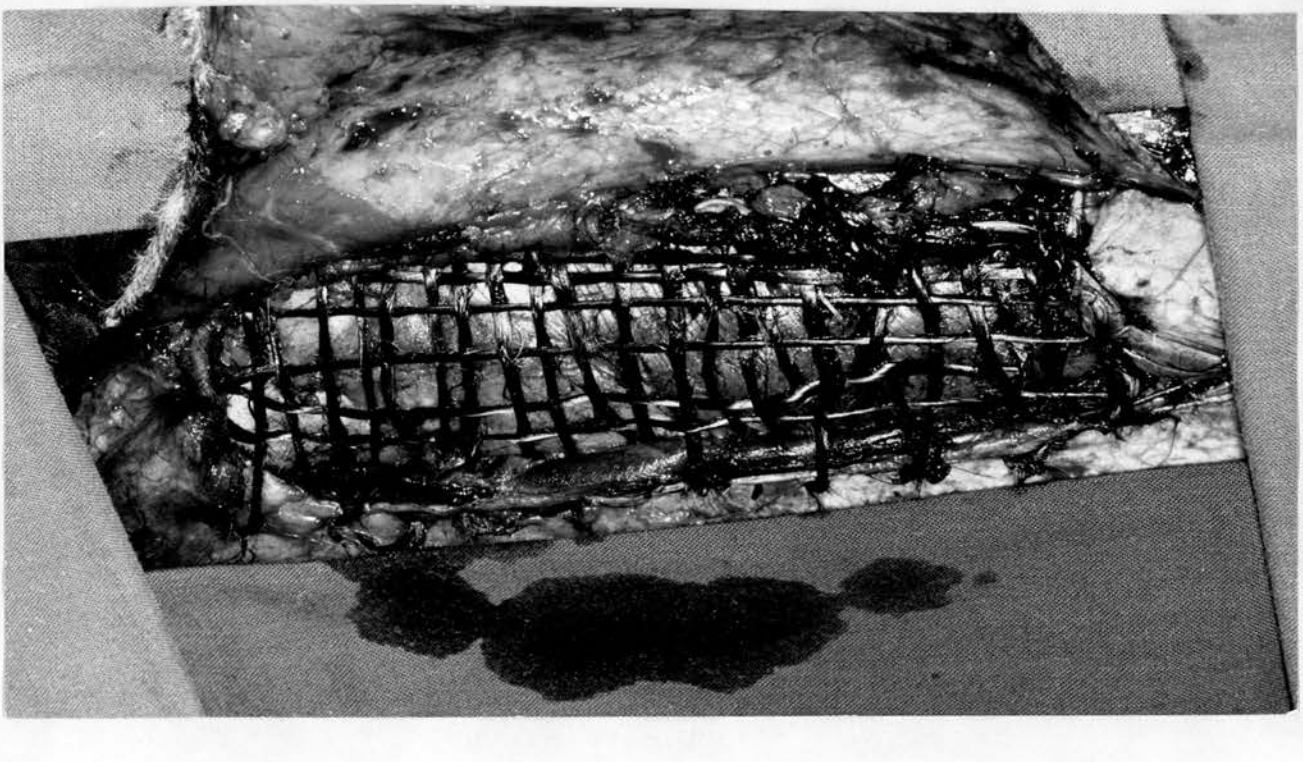


FIGURE 57. Repair of the ventral hernia by interweaving of filamentous carbon fibre to produce a lattice repair.

of the former at autopsy at three months, showed that the polyglycolic acid had become totally absorbed with the subsequent development of a ventral hernia. Examination at autopsy of the latter group, showed that the nylon had pulled free from the edges of the hernia site, resulting in a massive ventral hernia in each case. (Figure 58).

In the carbon group, one sheep developed a florid infection and was put down at six weeks. Four remaining sheep did not develop hernias, and it was apparent that the carbon fibre, interlaced in the manner shown in the accompanying illustration, satisfactorily supported the anterior abdominal wall, and the abdominal contents. (Figure 59). Histological examination showed massive development of fibrous tissue with the laying down of fibroblasts in the line direct strain. The appearances were not dissimilar to those seen in the newly induced achilles tendon in one of the former experiments described above.

From this initial pilot experiment, a more detailed examination of the use of this material, in the management of hernias in specially prepared sheep, is under way.

Uterine Prolapse in Sheep

In two sheep, uterine prolapse developed shortly following delivery. Following reduction of the prolapse and return to normal mobility, the prolapse recurred in each case.

The anterior abdominal wall of each of these two sheep was opened by a longitudinal midline incision and the uterus identified and thus reduction was completed. In each case, a single loop of filamentous

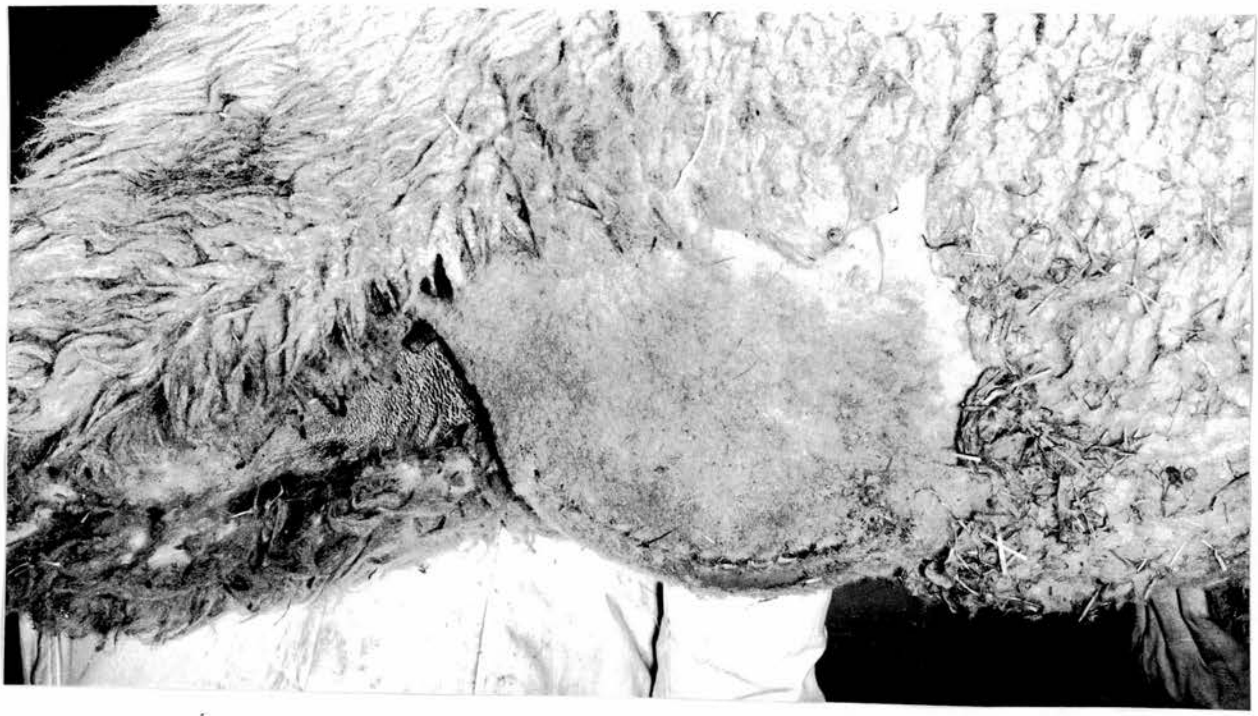


FIGURE 58. Development of a ventral hernia in a sheep repaired with polyglycolic acid interwoven in a similar manner to that used in the carbon group, three months post implantation.

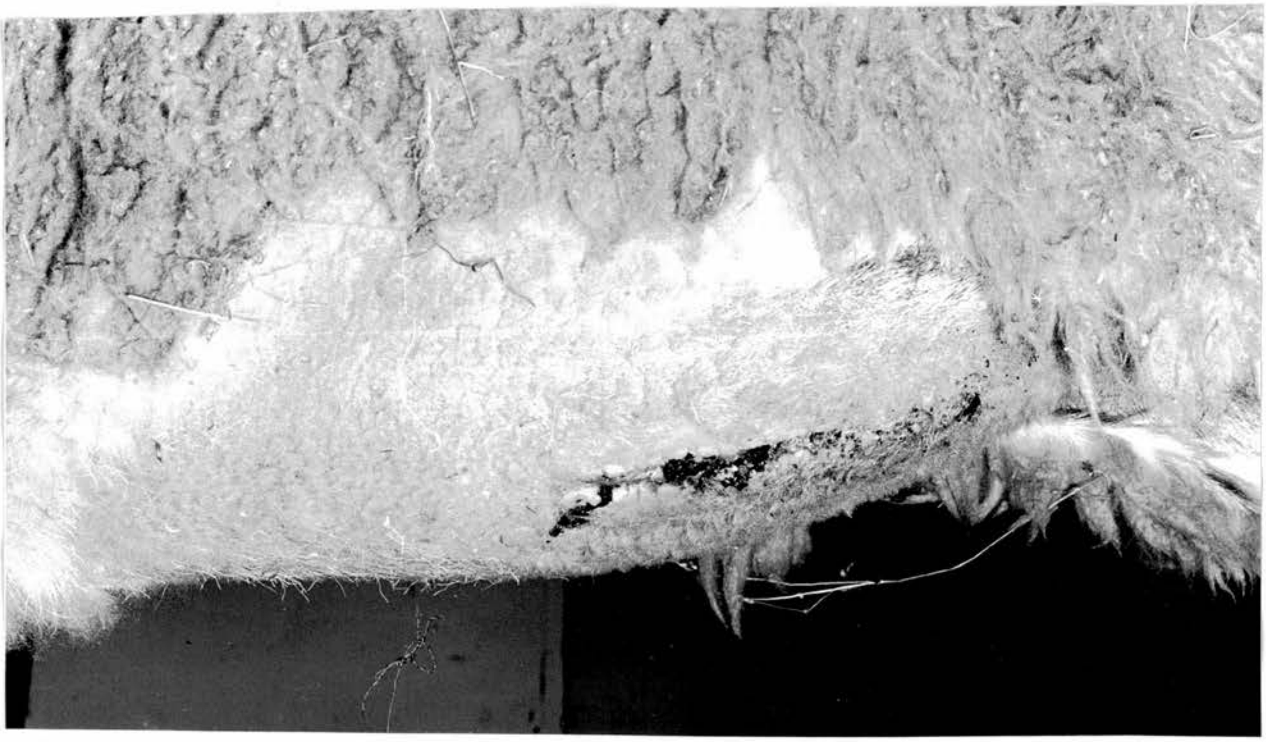


FIGURE 59. The appearance of the ventral surface of the sheep abdomen three months after repair with filamentous flexible carbon fibre.

carbon fibre was passed around the posterior part of the uterus at the cervico-uterine angle and then brought forward and more proximally to the anterior abdominal wall in such a way that a loose supportive sling of carbon fibre prevented uterine prolapse recurring.

Both sheep recovered satisfactorily and there has been no further evidence of uterine prolapse. One sheep became pregnant at a later date without further complications.

From this initial pilot experiment, arrangements are underway with the Department of Obstetrics and Gynaecology at the University Hospital of Wales to further examine this particular use of carbon fibre in the management of uterine prolapse in the human.

HUMAN USE OF FILAMENTOUS CARBON FIBRE

Approval was gained by the Ethical Committee of the University Hospital of Wales and by the Division of Surgery for implantation of filamentous carbon fibre into humans in certain selected orthopaedic conditions. In the choice of patients, certain criteria had been adopted:

1. Only patients with chronic ligamentous instability should be included.

2. Only conditions where tendon or ligament reinforcement or replacement frequently involves the use of other tendons or tendinous tissue should be included.

3. Patients in whom medico legal proceedings were pending or likely to occur, should be excluded.

4. Where possible patients should be elderly in view of the uncertain long term effects of carbon implantation.

HUMAN CARBON IMPLANTATION - PATIENTS

Patient T.G.B.

A fifty-six year old man with a left sided below knee amputation resulting from trauma was involved in a road traffic accident with severe subsequent damage to the lateral ligament and capsule of the right knee. His lateral ligamentous instability was of such a degree that coupled with his slightly reduced ambulatory capacity, because of the left lower limb prosthesis, his walking was severely compromised.

Under general anaesthetic, radiographs were taken with the knee in full extension and stressed in a varus direction. The instability of the knee was clearly demonstrated. (Figure 60)

The lateral aspect of the knee was exposed by a longitudinal incision and a hole drilled horizontally through the distal end of the femur at approximately 3cm proximal to the knee joint at a position which corresponded to the proximal end of the lateral expansion. An incision was made over the medial aspect of the femur 5cm above the knee and a double strand of filamentous carbon was led through the femur and fastened on the medial side by a single large knot. By trial and error the correct position of the tibial drill hole was determined and the double strand of filamentous carbon led across the knee joint in an extra capsular position and through the tibial drill hole and fastened on the medial side by three stout silk sutures with the carbon folded backwards and forwards upon itself. (Figures 61 and 62).

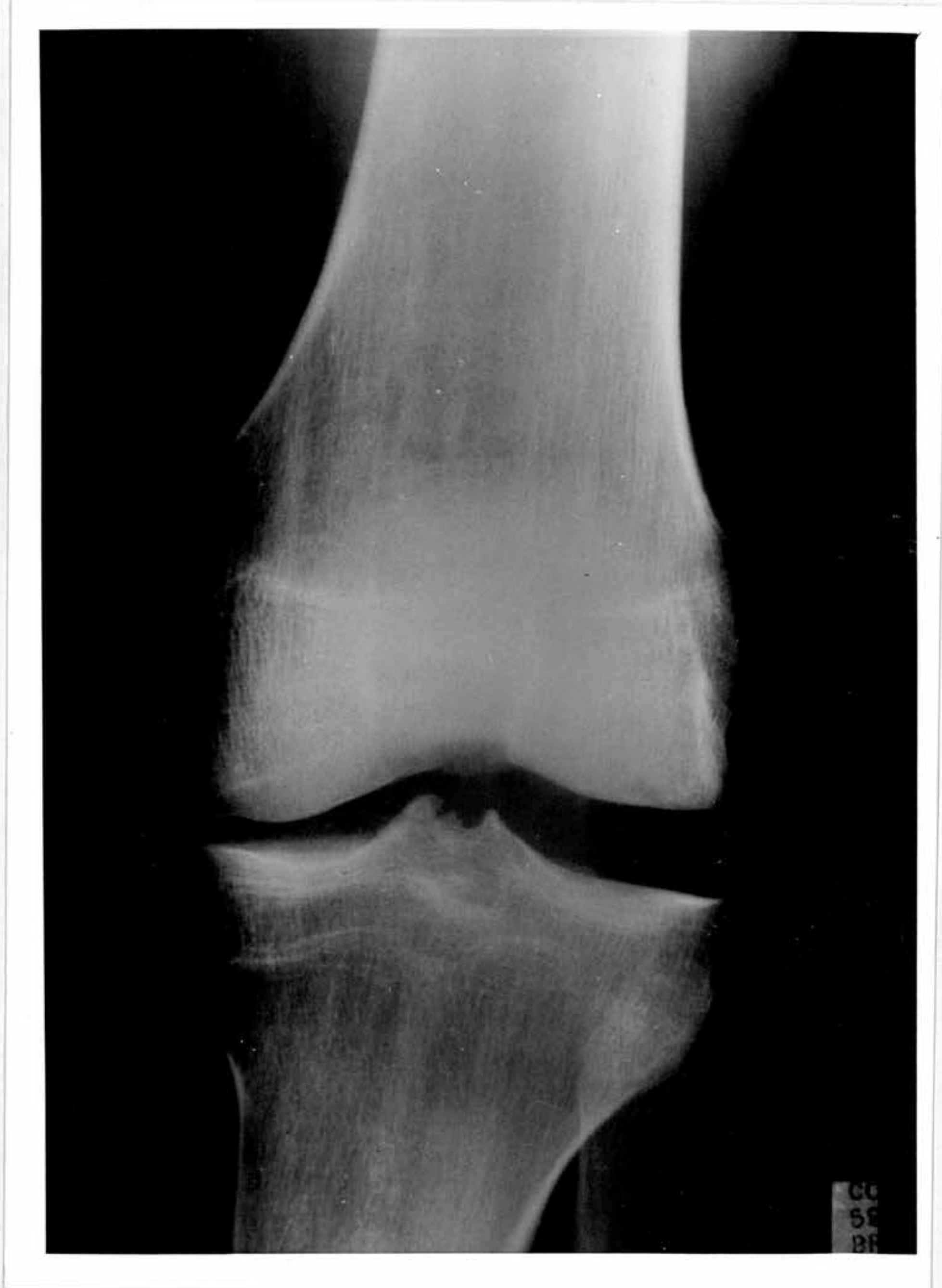


FIGURE 60. Patient T.G.B. Radiograph of the knee in full extension with varus stress applied under general anaesthetic.

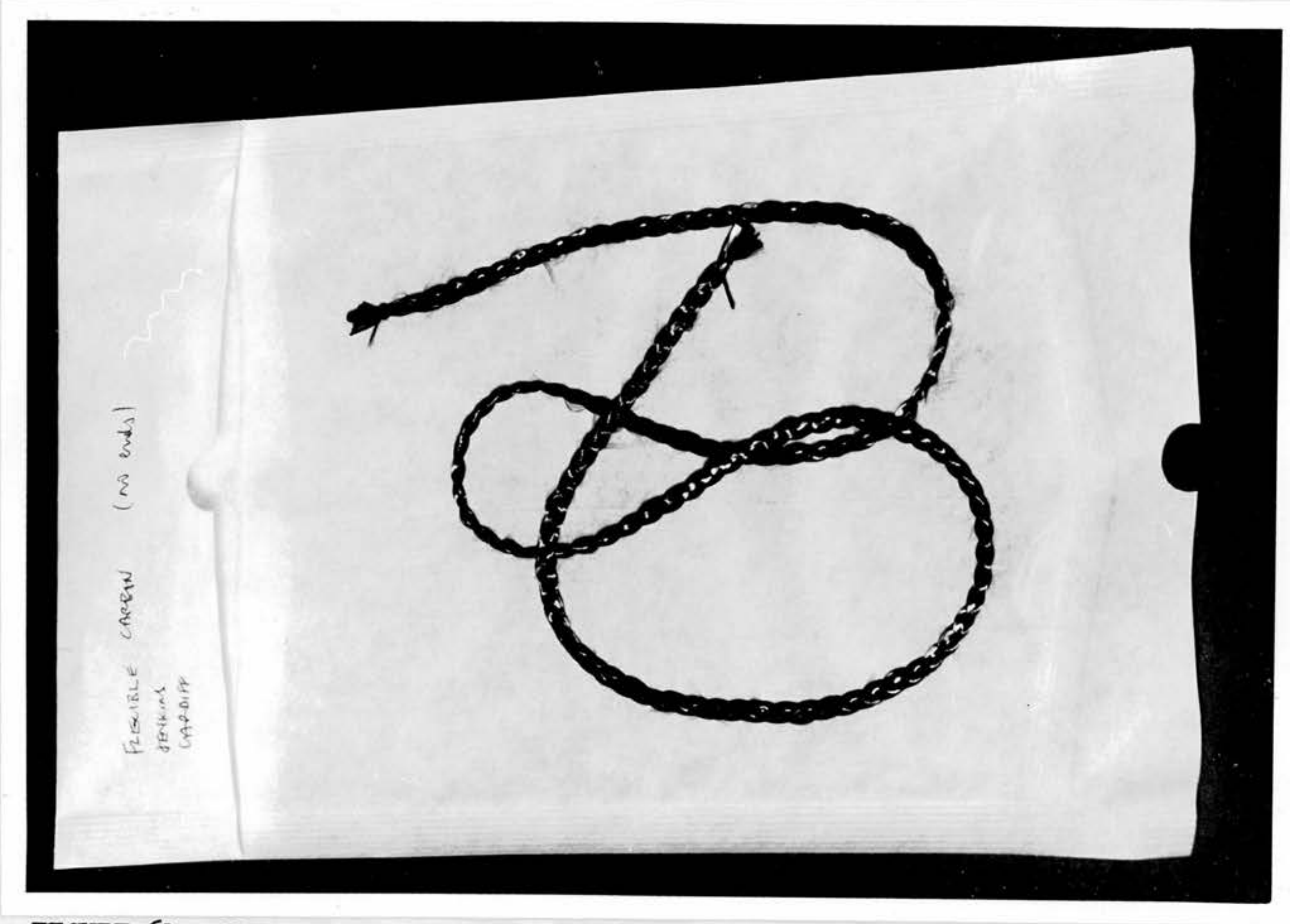


FIGURE 61. Heat sterilised carbon fibre prepared for implantation into patient T.G.B.

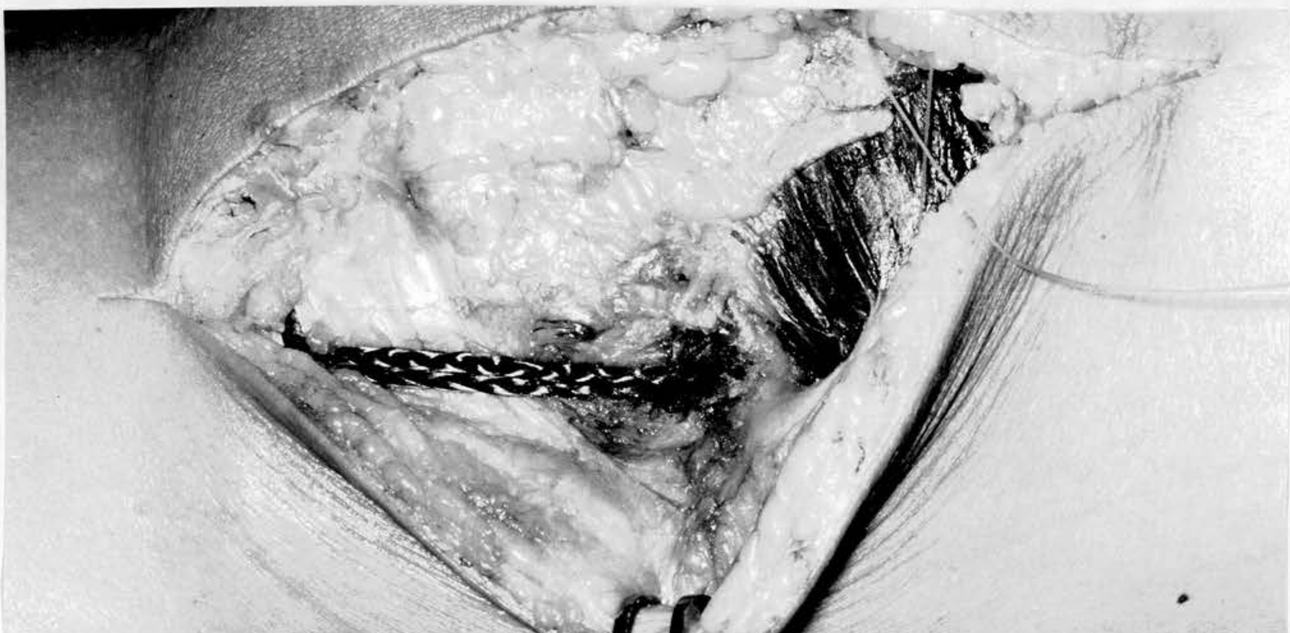


FIGURE 62. Reinforcement of the lateral aspect of the knee by extra capsular implantation of flexible carbon. Knee is in full extension.

At completion there was a full range of passive flexion and extension. In full extension there was no varus movement because of the reinforcement by the filament carbon fibre. The knee was held in 15° flexion in plaster of Paris for six weeks. Following removal of the plaster of Paris, wounds were soundly healed and the carbon strand could be felt as a cord beneath the scar on the lateral aspect of the knee. Within three months, a full range of movements of the knee were possible and the patient claimed that the knee was stable. (Figure 63). He has now been followed for fifteen months and the knee remains stable in full extension. It is now possible to feel a cord beneath the scar on the lateral aspect of the knee corresponding to the position of the carbon fibre implant, but at this stage, the cord has palpably increased in size to approximately twice its original bulk, suggesting that the presence of the carbon has induced a new bulky tendon-like structure to form at the implantation site.

Patient C.R.

A twenty-eight year old man with long standing metacarpo-phalangeal subluxation of the right thumb, (Figure 64) demanded a surgical procedure in order to stabilise the joint.

Under general anaesthetic, the MP joint was exposed through an S shaped incision and the capsular tear identified. (Figure 65). A double strand of filamentous carbon was woven across the joint and anchored in soft tissues only, in such a manner that at the end of the procedure the MP joint was stable. (Figure 66). The joint was supported in a scaphoid type plaster for four weeks. Following the removal of the Plaster of Paris, the joint was stiff, but normal mobility returned

FIGURE 63. The right knee is now stable : weight bearing photograph .

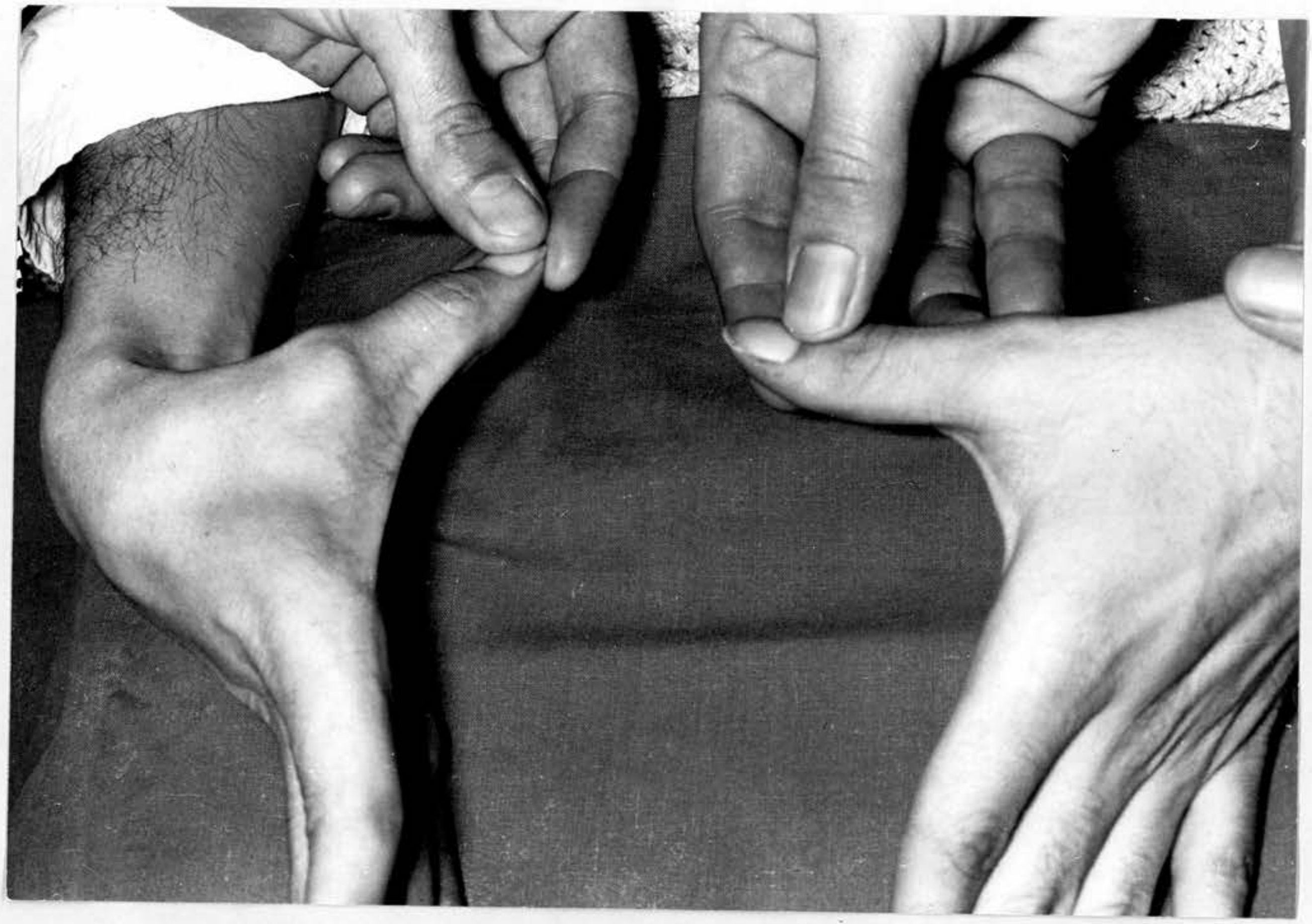


FIGURE 64. Right side metacarpophalangeal joint of the thumb instability due to subluxation of the joint secondary to a tear in the joint capsule.

FIGURE 65. Demonstration of the tear in the joint capsule.

1·0 cm

FIGURE 66. Stabilization of the joint by carbon implantation: insertion and fixation is extra capsular but anchoring is into soft tissue only.

1·0 cm

at two months. At six months, however, the patient again complained that the joint was unstable, and at nine months it was clear that no advantage had been achieved by this procedure.

Patient T.W.

A thirty-six year old ex-professional boxer presented us with a similar complaint to the second patient. He claimed that the subluxation and subsequent instability of the MP joint of his left thumb made his job of a cranedriver almost impossible.

Under general anaesthetic the MP joint was exposed by an S shaped incision and repaired using filamentous carbon fibre. In this patient, however, two smallholes were drilled, transversely through the distal end of the metacarpal and proximal end of the proximal phalanx and the carbon fed through both drill holes and across the joint in a figure of eight position in such a manner that the joint was rendered stable. Following removal of plaster at one month, the joint was stiff but stable and at three months, full mobility had returned.

It is suggested that the inadequate anchoring of the carbon in soft tissue alone as in the second patient, led to inadequate reinforcement of the MP joint, but that in Patient No.3, where the carbon was led through the bone, the anchoring points prevented the carbon tearing free, and thus resulted in longer term stability, allowing satisfactory fibroblast ingrowth to occur.

Patient P.H.

A seventy-six year old female with established rheumatoid disease and subsequent left knee instability was examined under a general anaesthetic and stress views of the knee taken. A valgus strain view showed an instability of 20° and a varus strain view and instability of 15°.

Following the early success with the first patient, it was decided to reinforce the medial and lateral ligaments of the knee, using filamentous carbon fibre.

A suitable double strand was prepared and by appropriate horizontal drill holes through the tibia and femur, the carbon was fed through and across the joint in such a way that stability was restored. In this patient the carbon was fed through in an extra capsular position via a subcutaneous route, thus avoiding unnecessary large scars on the medial and lateral aspect of the knee. In this way, the carbon was passed in a full circle across the femur, across the medial aspect of the joint, through the tibia, and across the lateral aspect of the joint, and then tied upon itself at the lateral femoral drill hole site. The knee was immobilized in Plaster of Paris for six weeks and following removal of the plaster, only 30° knee flexion was possible. At four months 30° flexion was all that could be achieved and the knee was therefore gently manipulated under anaesthetic. In full extension, under anaesthetic, the knee had remained stable. Following gentle manipulation, knee flexion to 90° was achieved, and this has been maintained for the last seven months.

Patient C.C.

A twenty-six year old bank clerk had sustained a severe medial complex tear to the right knee whilst playing football and had subsequently undergone surgical repair, without success. Two years following the accident, he was unable to run, and his sporting activities were therefore severely curtailed.

Under general anaesthetic, stress views of the knee were taken, confirming the medial ligamentous instability of the knee.

The medial capsule and ligament were reinforced using a double strand of carbon fibre led through suitable drill holes in a subcutaneous route and anchored on the lateral side. (Figures 67 and 68). Following immobilisation in plaster for six weeks, he achieved full range of movement by four months, and has since returned to light jogging. He claims that the knee, while not as fully stable as that on the opposite side, does not give way and that he is able to run gently without difficulty.

He has been followed for five months.

Patient B.C.

Following an accident fifteen years before his attendance at my clinic, this man had sustained tear of the lateral ligaments of the left ankle which had resulted in a large number of painful episodes when the ankle had collapsed beneath him in a varus position. Stress views taken under general anaesthetic confirmed the lateral ligamentous instability. The lateral malleolus and lateral aspects of talus and os calcis were exposed by a longitudinal incision and a suitable drill hole made in the distal end of the fibula. A suitable tunnel was prepared in os calcis measuring approximately 4cms in length and a single strand of filamentous carbon fibre fed through the fibula and through the tunnel in os calcis in such a manner that a triangle of carbon fibre supported the ankle and sub talar joints in an extra capsular position. The ankle was immobilised in a below knee walking plaster for six weeks. One month following removal of the Plaster of Paris, there was a full range of ankle movements, but sub talar movements in a varus direction

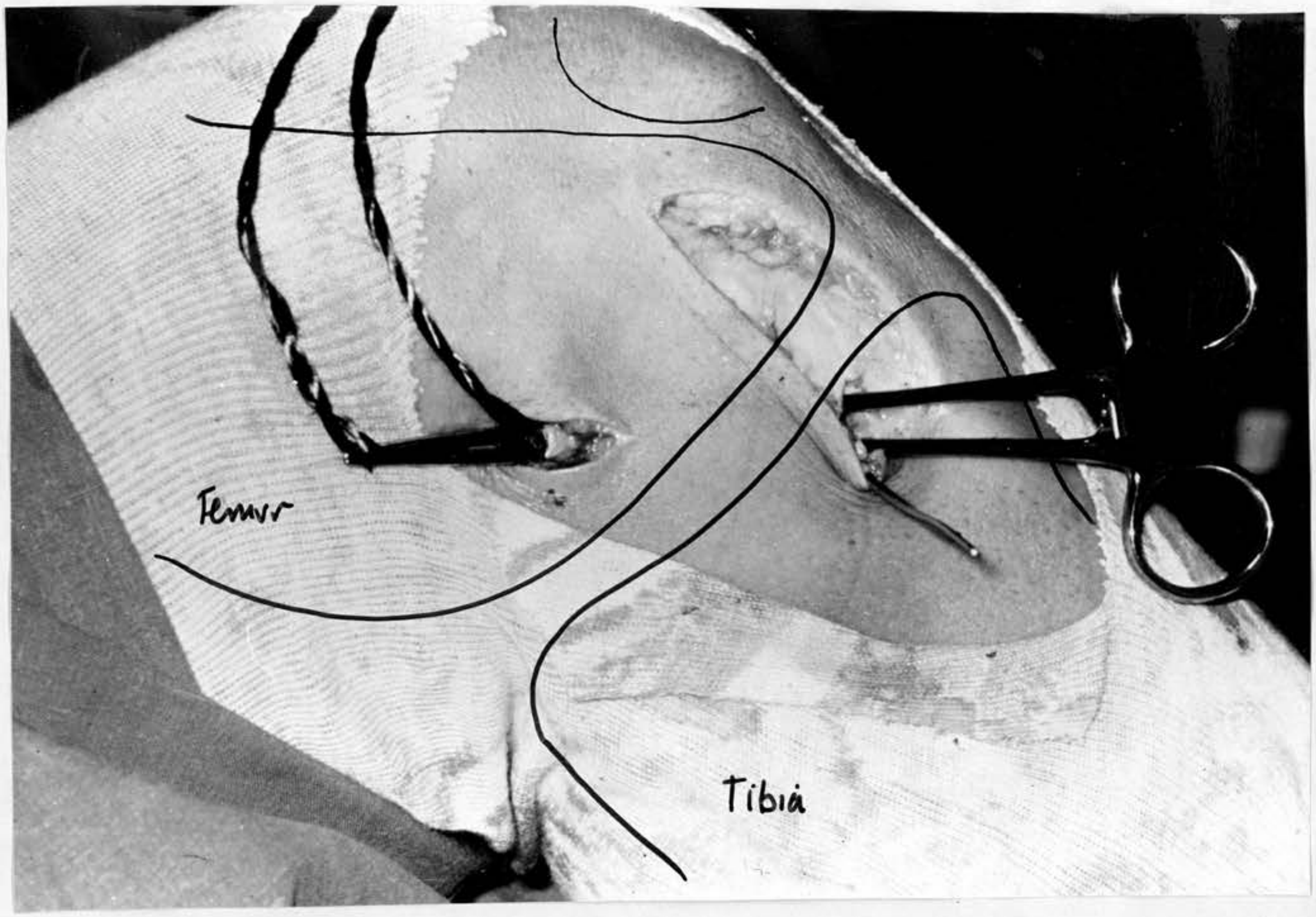


FIGURE 67. Carbon is fed across the knee joint by subcutaneous route

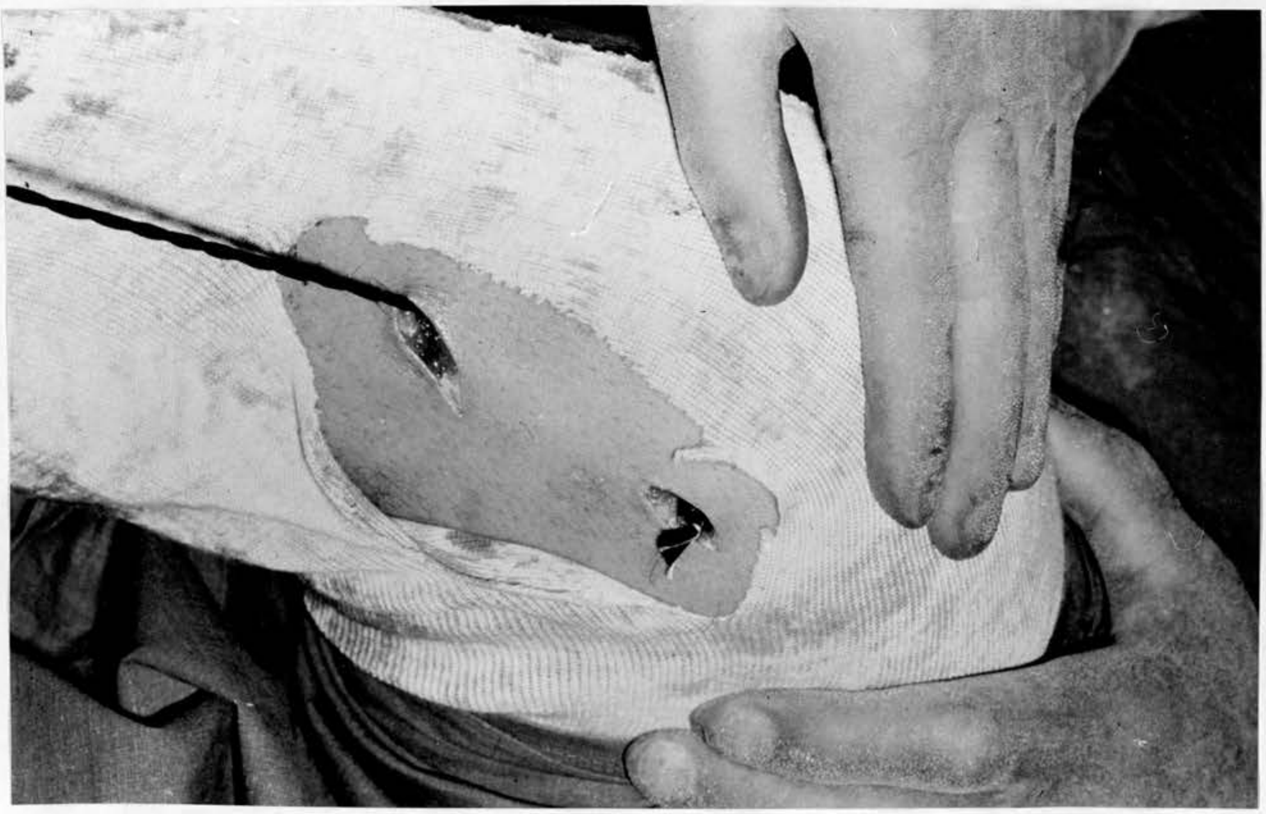


FIGURE 68. Carbon has been passed through femur, across the joint in an extra capsular position and back through tibia. When pulled tight with the knee in slight flexion, the carbon is ready to be fastened by knotting and suturing to the periosteum of the tibia.

were severely curtailed The patient has now been followed for five months. The ankle has not given away beneath him and he suffers no pain. He is aware of the slight limitation of sub talar movements which have persisted.

Patient A.C.

A thirty-year old girl who had suffered from anterior poliomyelitis as a child had difficulty with walking because of a left foot drop. Our initial plan was to perform a standard form of tenodesis using tibialis anterior or peroneal tendon, but in view of the early success with the carbon fibre in other patients, it was decided to perform a tenodeses using carbon fibre.

Appropriate drill holes were made in the distal end of the tibia and across the talo-navicular joint, and a single strand of carbon fibre led through the two holes and beneath the extensor retinaculum in such a way that the foot was pulled in a more dorsal position. Elongation of tendo achilles was also performed. Following immobilisation in plaster for six weeks, the foot did not collapse in a plantar direction and this satisfactory position has been maintained for four months.

Patient T.P.

A sixty-year old male plumber had sustained a knee injury eight months prior to presentation at my clinic while playing football with his grandchildren. The knee had given away during a twisting movement and since that time, he had been troubled by the knee locking and giving way beneath him. Examination without anaesthetic suggested that there was an anterior cruciate tear. Arthrography suggested that the meniscae were intact. Provocative exercises failed to produce any improvement and at arthrotomy, the anterior cruciate was found to be divided. There was a small tear in the anterior pole of the medial meniscus. Medial menisectomy was performed. In view of the marked anterior draw sign and the man's prime complaint of knee instability, it was decided to replace the anterior cruciate using a single strand of plaited carbon fibre. Suitable drill holes were made in such a manner that the strand of carbon fibre could be passed across the knee joint in the anatomical position of the anterior cruciate ligament. The carbon was fastened by three stout silk sutures on the lateral cortex of the femur and medial cortex of the tibia and before closure it was ascertained that a full range of passive movements was possible. The anterior draw sign with the knee in 90° flexion was no longer positive because of the presence of the carbon fibre. The knee was immobilised in Plaster of Paris for twenty days and sutures removed at three weeks. Within one month, 90° knee flexion had returned, and four months later, he was able to run without the knee giving way.

Patient E.P.

A thirty-four year old male was playing football and during the game he kicked a ball over his head, as he did so, he felt something give in his knee and he collapsed to the ground in pain. He treated his knee discomfort with bandaging at home and presented himself four weeks later to my outpatient clinic with a complaint of continued pain and knee instability. Examination showed a marked positive anterior draw sign. At medial arthrotomy, the anterior cruciate was found to be torn from its tibial origin. The anterior cruciate was replaced in the anatomical position with a single strand of filamentous carbon fibre. Following immobilisation in Plaster of Paris for twenty days, the knee was left free and sutures were removed at three weeks. One month later, he only had 30° flexion, but three months later he has developed 90° knee flexion, and the knee remains stable.

Patient H.J.

A fifty-four year old lorry driver, measuring 6'3" in height and weighing 210 lbs jumped from the cab of his articulated lorry and landed awkwardly. As he did so, he felt his knee give way beneath him and was subsequently shown to have an anterior cruciate tear. The anterior cruciate was replaced in the manner described for the other patients and four months following repair, he has now returned to work as a heavy goods vehicle driver with no instability and a good range of knee flexion.

Patient D.F.

A forty-eight year old man presented with a long history of discomfort over the lateral aspect of the left ankle and the ankle frequently giving way beneath him. Stress views under general anaesthetic confirmed the presence of a tear of the lateral expansion and the lateral ligament was replaced in the manner described for the previous patient with a similar injury. The results were similar in that the ankle remained stable with limitation of subtalar movement. The patient has remained pain-free for the last six months. He claims that the slight limitation of subtalar movement causes him no problem and that he is happy with the result.

Patient B.K.

A thirty-six year old ex professional ice-skater had been forced to cease her profession because of lateral ligamentous instability of the left ankle following a series of skating accidents. Stress views confirmed the instability. Figure 69.

In view of the slight limitation of subtalar movement induced in the two previous patients with this condition, the more correct anatomical procedure of fibulo-talar ligament repair was attempted, using filamentous carbon fibre. In this procedure a drill hole was made through the distal end of the fibula and a suitable hole made across the width of the talus to the medial side. A second drill hole was made across the talus 2cms behind the first and a suitable strand of filamentous carbon fibre fed through both drill holes and through the hole in the fibula in such a manner that the lateral aspect of the ankle joint was rendered stable. (Figure 70). The exact positioning of the drill holes proved awkward, and it is planned that in the next patient, radiological control will be used for the siting of the drill holes. She remained in a below knee plaster for four weeks, and eight months later has now returned to skating for pleasure although she has not attempted competitive skating.

FIGURE 69. Patient B.K. Stress views of the ankle taken under general anaesthetic.

FIGURE 70. Patient B.K. Stabilisation of the lateral aspect of the ankle by extra capsular plication with carbon passed between fibular and talus and passed through each bone as shown.

FIGURE 71. Weight bearing view of both ankles at eight months post implantation. The carbon cannot be seen because it is radiolucent (atomic weight 12).

DISCUSSIONS AND CONCLUSIONS

The use of carbon as an alternative to prosthetic material is based on the supposition that in the forms chosen, it offers an alternative to the established implants without some of their disadvantages and with additional advantages.

It has been seen that conventional and other more experimental implant materials are not entirely perfect, particularly on the grounds of questionable biological acceptability.

While it is true that all molecules of living tissue contain carbon, it is not correct to assume that this alone assures the biological inertness of carbon as an implant. However, it is perhaps significant that the majority of implants are composed of carbon atoms in conjunction with other atoms and it might be argued that the presence of other atoms or their conjunction with carbon is responsible for adverse tissue reactions. Exceptions to this suggestion are pure metals, of which titanium is amongst the most inert. The large polymers have been shown to have varying degrees of tissue acceptibility and those of high molecular weight generally have the greatest degree of biological inertness.

The questions to be asked, therefore, are:

1. Is carbon in the form used inert?

2. Does it produce any undesireable reactions in living tissue?

3. Has carbon a structural form satisfactory for prosthetic use?

Tissue Reaction to Implants

The foreign body reaction has been discussed and experiments with carbon in its various pure forms described. The conclusion is offered, from the basis of the experimental work, that pure carbon is biologically inert. This does not imply that there is no tissue reaction but it does suggest that the response of living tissues to carbon is not that normally seen to foreign bodies. There is, for example, practically no giant cell response, but there is a response to flexible carbon by massive fibrosis which develops in response to the flexible carbon implant. When carbon is implanted in rigid form, there is no fibrous response implying that the tissue reaction is one to the physical nature rather than the chemical composition of the implant.

Adverse tissue reaction to foreign implants include:

a. Tumour Formation

Phenolformaldehyde has been shown to induce tumour formation in rats (Turner 1941). Tumour formation secondary to exposure to materials has been established since the classical work of Pott in 1775 who noted the development of epitheliomas in the scrotum in those in prolonged contact with hydrocarbons (Willis 1967). Kennaway (1930) established that the hydrocarbon 1,-2,-5,-6, dibenzanthracene was carcinogenic and it is pertinent to this thesis to note that this is a long chain molecule, largely composed of carbon but in association with other atoms and in such a configuration which makes it carcinogenic. Oppenheimer, Oppenheimer, Stout and Eirich (1955) in their systematic study of materials which will induce tumours in animals have shown a wide variety of carcinogens all of which are long chain molecules, but they also noted that the rate of tumour induction varied with the physical form of the material. Plastic films containing benzyl peroxide (an organic catalyst in many commercially available plastics) readily induced fibro-sarcomas in rats. Plain films however, produce a higher proportion of tumours than plastic mesh, powder or fabric. The suggested reason for this observation was apparent partial tumour inhibition by the ingrowth of fibrous tissue into perforated plastics with ready degredation into carcinogenic monomers of the plain film. Danishefsky, Oppenheimer, Herriter-Watkins, Bella and Willhite (1967) examined the biochemical changes which accompanied the development of a fibrous capsule around an established carcinogen and concluded that the environment produced around the foreign body somehow suppressed metabolic activity, thus reducing the incidence of malignant change.

In our experiments with carbon implantation, there have been no examples of tumour formation. While one cannot extrapolate with total reliability from the animal to the human, it is suggested that, from the evidence presented, carbon in the forms described, is not carcinogenic.

There are well established examples of carbon implantation without adverse effect and the best of these is in the tattoo. The pigment of tattoo is carbon dust, as used in Indian Ink. Certainly, tattoos are not entirely innocuous but the problems associated with them are those of infection and associated with substances other than pure carbon. The prolonged habit of tattooing without evidence of carcinogenisis or other adverse response to carbon goes some way to create a precedent, for its safe use. There have, however, been occasional reports of malignant change in association with tattoos, but the cause of the relationship with the carbon is doubted since the purity of the implant is not of the best. Kirsch (1972) has drawn attention to this very occasional association. An argument can be presented for its safe use from the physical nature of the implant. The flexible form, which is in effect a mesh, is similar to other mesh like fabrics such as silk in suture materials. Such substances promote a response which is the standard foreign body response and differ in this respect from the carbon which promotes no such response. The implication is that silk and similar meshes promote such a response because of their chemical rather than their physical nature.

Carbon dust is frequently inhaled by all city dwellers and while there is no direct correlation between it and malignant pulmonary change in this situation, there has been some suggestion that high rates of inhalation are responsible for adverse reactions. The graphite pneumoconiosis in coal workers, while it may be associated with superimposed tuberculosis, is a fibrosis of the alveoli and is presumed to be due to carbon dust (Uragoda 1972). While there is little doubt that carbon dust in the lungs does produce fibrosis, there is no evidence to implicate pure carbon as a carcinogen. Moody (1975) has drawn attention to the different response of lung parenchyma to silica and carbon, and McIntoch (1975) suggests that lung carcinomas are not necessarily related to carbon inhalation. The Registrar General's Report (1961) goes so far as to state that exposure to coaldust (not even pure carbon) does not necessarily increase the risk of lung carcinoma. Thus, evidence at this time suggests that even prolonged exposure to high quantities of carbon dust in the inhaled air does no more than encourage fibrosis, and it is probably not at all carcinogenic.

However, the question of carcinogenesis is one which cannot be lightly dismissed; for this reason, prolonged animal experiments and limited human use are planned.

Infection

Infection is, by definition, the reaction of living tissues to living organisms, bacteria, yeasts, fungi, and viruses. Infection in association with an implant is therefore not primarily due to the implant itself, but due to a second foreign body, namely the organism.

The pathogenicity of an organism can be increased by the presence of a foreign body. This is thought to be due to the presence of the protein rich exudate which develops in response to a foreign body which may encourage bacterial growth and fertility, all due to the possible shielding effect of the implant which inhibits the normal defence mechanisms on living tissue (Everett 1970). Everett has noted that different suture materials are associated with different infection rates and cites the example of silk and catgut. The former, while exciting the foreign body reaction, does so to a lesser extent than the latter and is associated with a lesser rate of infection. (Alexander, Kaplan and Allemeyerha 1967).

Carbon in its flexible form might thus be expected to be associated with a lesser rate of associated infection.

There is no evidence at the moment to support this supposition, but there is none to the contrary, except that in the experiments described on rigid carbon plating, all implants, both metal and carbon, became infected with a faster epithelealisation rate in the carbon animals, thus suggesting that perhaps infection is a lesser problem with the carbon.

Lymphoreticular Blockade

The fragmentation of carbon from the implantation site has been suggested to be an advantage in that it represents removal of the implant with the development and retention of normal active tissue in its place.

However, the carbon, following fragmentation, enters the lymph system and is collected in the regional nodes. The effect on the local lymph system is not fully established, but the results described indicate that the local nodes are well able to tolerate the carbon particles.

That carbon readily enters the reticuloendothelial system has been recognised and used without detriment in the now established carbon clearance test for in vivo phagocytosis (Wier 1973). This work, based on the system developed by Biozzi, Halpen, Stiffel, and Benacerraff (1954) uses colloidal carbon particules injected intravenously and this is followed by removal of the carbon by the intravascular phagocytes in liver and spleen. The rate of removal by the Kupffer cells and splenic macrophages is a measure of reticulo-endothelial phagocytic activity. Massive injection of carbon results in some absorbtion of carbon by the parenchymatous cells of the liver, but does not produce a significant adverse respnse (Stiffel, Monton and Biozzi 1970). Others have demonstrated the use of carbon without detriment in similar fields of study (Sutton 1975, Van Ginckel 1975, Bankstrom 1974).

It has been demonstrated that carbon particles do readily enter the reticuloendothelial system following implantation in the experimental animal, and it is assumed that the same events occur in the human. The rate of removal from the implantation site is extremely slow. The volume of carbon implanted is low in relation to the size of the whole animal or human, and in comparison with the weight of carbon used in the experiments on lymphoreticular blockade referred to above, is proportionately small. With this experimental background, I regard the use of carbon in the pure state and in the small amount implanted, as safe and without hazard to the reticuloendothelial system.

At the time of writing,the results of experiments on the rigid carbon-reinforced-carbon and carbon composites are inconclusive. There are suggestions only that the carbon and/or carbon composites may have a use in the form of bone plates. It is not proposed to comment at length on the potential uses or potential results, but the intention is more to comment on the reason why carbon may offer some advantage over conventional simple implants.

The wear properties of carbon have not been determined and no experiments have been conducted to date on the potential use of pure carbon in joint replacement surgery. However, some of the results described imply that rigid carbon may have some potential in this field.

The possible advantages of rigid carbon are as follows:

Radiolucency

It is conventional to assess supported fracture healing by both clinical examination and radiological assessment. If a form of internal fixation is truely rigid, clinical examination will do no more than confirm the continuing rigidity of the implant or its fixation to bone.

Radiological assessment is readily made, but the presence of a metal plate obscures some part of the fracture site. Carbon with its low mollecular weight of 12, is non radio opaque and thus visulisation of the whole bone surface and fracture site is achieved.

Modulus of Elasticity

The elastic modulus of bone has been established as 1 - 3 x 10^6 p.s.i. (Swanson 1971). Carbon-reinforced carbon can be manufactured with a similar modulus of elasticity by varying thickness and fibre orientation (Jordan 1976). Similarly, carbon composites can be produced with the same mechanical properties (Woo, Akeson, Levenetz, Coutts, Mathews and Amiel 1974). Recent evidence has confirmed that rigid internal fixation produces pronounced ostopenia in the cortex directly under the plate, reduction in shaft callibre (caused by periostial resorption) and persistance of woven bone at the fracture side in the place of cortical bone (Uthoff and Dubuc 1971). The potential weakness of an overprotected bone due to excessive rigidity in fixation by metal plates and the potential advantage of a form of fixation of similar elastic modulus to that of bone suggests that if such a material can be found, it might replace the conventional metal systems in use. The experiments described attempt to explore this possibility, but it is not readily recognised that technical consideration in methods of fixation are of equally great importance as the nature of the material used for the fixation device. It is anticipated that the further planned experiments will demonstrate whether the potential advantages are, in fact, correct.

Biological Inertness

Evidence continues to accumulate which suggests that carbon is inert. The occasional presence of giant cells about carbon composite implants and the virtual absence of such indicators of tissue reaction about carbon-reinforced carbon implants, suggests that pure carbon evokes the same negative response whether in particulate or rigid form. The main potential advantage in carbon composites lies in their easy manufacture, commercial availability, and elastic modulus while the main potential of carbon-reinforced carbon lies in its apparent total biological inertness and elastic modulus.

Macrophage Destruction of the Implant

The presence of carbon particles about a rigid carbon-reinforced carbon implant in adjacent soft tissues suggests that rigid carbon may undergo slow fragmentation at the site of implantation. Whether this represents the same type of fragmentation as that seen in the flexible carbon is not entirely clear. Certainly no lymph node specimens in the rigid groups showed any carbon deposition, but the comparatively short length of time over which the carbon plate experiments were conducted may be responsible for the lack of proximal lymph node deposition. If it is shown that carbon particles are found in regional nodes following implantation of rigid carbon, then an intriguing question is posed: Can the carbon plates be regarded as a temporary implant which will gradually disappear from the site of implantation, and if so, what is the long term effect of carbon deposition in large quantities at the regional nodes? The latter part of this question is discussed in the section on flexible carbon which follows. The former part of the question can not be answered as yet, but the presence of carbon particles in adjacent soft tissues at periods of three to six months post implantation might suggest that the answer is in the affirmative.

Epithelialisation

The theoretical advantage of an implant which epithelialises has already been mentioned. The carbon-reinforced carbon under test is certainly different in nature to that used by Mooney, Hartman, McNeal and Benson (1974) in their successful use of carbon for percutaneous electrical connector systems. The pure chemical nature of their vitreous carbon, and the carbon-reinforced carbon described in this thesis, together with the promising epithelialisation described, would suggest that epithelialisation and acceptance of carbon is a repeatable experimental finding, and may hold promise in fixation of fractures where skin loss is a major problem.

Fixation

The experiments described on the low electro-motive force generated by different conventional metals with carbon in an in vitro physiological environment, suggests that metal screws can be used with safety in fixation of carbon plates. However, further experiments are planned in which carbon coated screws will be used with metal or carbon coated metal plates.

The experimental results with rigid carbon-reinforced carbon and carbon composites are presented as preliminary examinations and no firm conclusions have been drawn. The experiments with flexible carbon are presented to demonstrate the development of the material, both short and long term results, and together with the clinical series involving carbon plaits described, some conclusions are reached.

Flexible Carbons

The implications drawn from the experimental work on flexible carbon are that it will act as a suitable ligament replacement material and may act as an alternative material in tendon prosthetics because of its unique properties.

All current methods of tendon or ligament replacement or augmentation, rely on a system of transplantation of autologous tissue from one site to another, or replacement with a foreign material substitute. The inversion injury to the ankle producing chronic instability due to tear of the lateral ligaments, is frequently repaired by peroneal tendon transfer (Watson Jones 1955) and is one example of tendon transplantation. While frequently performed, it has the double disadvantage that it requires the loss of some normally functioning tendon and is not always successful (Anderson and Lecocq 1954). Tears of the cruciate ligaments of the knee frequently require elaborate rerouting procedures with adjacent tendon like tissue without uniformly satisfactory results (O'Donaghue 1963). The difficulties experienced in many situations such as the two examples given, have led to a variety of alternatives where the advantages of leaving remaining tissue intact have not produced uniformly satisfactory results.

Tendon and ligament substitutes have been studied and have enjoyed some clinical uses since the earliest part of the twentieth century. Development of more inert materials and the satisfactory bonding of one material with another has led to some satisfactory ligamentous substitutes.

Henze and Mayer (1914) demonstrated the limited use of silk as a tendon substitute but the material never entered common clinical use in this situation. Of the later alternatives, wire (Arkin and Siffert 1953), Teflon (Williams 1960), Silicone (Border and Curtin 1968) and mixtures such as Silastic with Dacron (Salisbury, Mason, Levine, Pruit and Wade 1974) have all been used.

They all have one severe drawback and that is that however strong and flexible the material may be, they do no more than simply replace the original living tendon or ligament. In this, they act in the manner of a cord which at best, does no more than mimic the action of the original tissue.

The flexible carbon, however, behaves quite differently.

There is little doubt that filamentous carbon is fibrogenic. When placed in position, whether in muscle, fat, or epithelium, it induces fibrosis. Since it appears to be practically inert, one may speculate that the fibrosis is due to the physical and not the chemical presence of the carbon. In this respect it may induce fibrosis by abrasion or physical irritation. However, when placed in a functioning position, such as in the replacement of tendo-achilles or cruciate ligament, it not only attracts connective tissue ingrowth with the laying down of substantial deposits of collagenous fibres, but the collagen fibres gradually orientate themselves in one direction along the lines of stress. The three types of tissue reaction have been described in which, in the first instance, there is initial fibrosis around the periphery of the carbon implant. Secondly, the ingrowth continues, and gradually, the carbon filaments are pushed apart and thirdly, high collagen production and abundant fibrosis follows with the development of a complete structure closely resembling normal ligament. The initial fibrosis precludes its use at this time in tendon replacement where wide travel of the tendon in required, such as in the flexor tendons of the hand.

The suggestion is made that the gradual mechanical failure of the carbon is the root of its success by allowing a gradually increasing load to fall on the newly developed collagen, thus allowing it to become orientated in the lines of stress. If the strength of the implant had been maintained, the collagen would have been protected from stress, so that the orientation would have been haphazard as was found in the non-stressed implants into non load bearing soft tissue. The histological evidence appears to support the fragmentation theory.

The final question to be answered is one of the possible use of filamentous flexible carbon in the human.

It is well recognised that any new implant material may possess inherant hazards which will not be recognised for many years. The early work with basic plastics and the resultant carcinogenic properties of these materials, acts as a ready warning against excessive premature enthusiasm. However, there are precedents already referred to such as carbon in the lung parenchyma, and adjacent regional nodes in city dwellers which suggest that carbon is a safe implant material. With such precedents, it was felt that carbon could be used in a limited clinical trial following approval by the local Ethical Committee and the Division of Surgery at the Welsh National School of Medicine.

The clinical trial has been started and the early clinical results are encouraging. It remains to be seen whether the animal experimental results are applicable primarily to the animals examined, or whether this material will eventually earn a place in both veterinary and human practice as a tendon or ligament prosthesis.

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PATENTS

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INDUCTION OF TENDON AND LIGAMENT FORMATION BY CARBON IMPLANTS

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Experiments have been performed on rabbits and sheep which demonstrate that pure carbon, in a flexible and filamentous form of great strength, can be used successfully to induce the formation of new tendons. A concept fundamentally different from that underlying the use of other artificial tendon replacements is involved, in which rapidly developing tendon-like tissue is induced to form around the implant. This gradually takes over the function of the implant. The early results in rabbits and the late results in sheep suggest that filamentous carbon may have a place in the replacement of the calcaneal tendon and the collateral ligaments of the knee.

Since a high proportion of the tissues of living organisms is composed of carbon compounds it would not perhaps be surprising that implants of the pure element should be well tolerated by these tissues. Evidence continues to accumulate which appears to bear out this expectation, and successful implantation has been reported with a wide variety of types of carbon. Vitreous carbon (North American Rockwell Corporation 1969; Jenkins and Kawamura 1971; Mooney, Predecki, Renning and Gray 1971; von Fraunhofer, L'Estrange and Mack 1971; Mountvala 1973; Mooney, Hartman, McNeal and Benson 1974) as well as porous and solid carbon composites (Janeke, Komorn and Cohn 1974) have all shown a high degree of tissue compatibility.

This report is concerned with the use of another form of the element, filamentous carbon, as a means of inducing the formation of new ligaments and tendons. Filamentous carbon differs from some other forms of commercially available carbon in that it consists of nothing but the pure element and, as its name implies, it is flexible. It is produced as a twist free tow containing approximately 10,000 individual elements 9 to 10 microns in diameter (Courtaulds U.K. "Grafil" H.M.S.) consisting of carbon atoms linked in an orderly manner which gives it both strength and flexibility (ultimate tensile strength 2·1–2·35 GN/m^2, modulus 310–345 GN/m^2). The individual fibres are rather brittle but it can be plaited to give a sound cord-like structure (Fig. 1). In this form it has been used as a substitute for the tendo calcaneus in sheep and rabbits and for collateral knee ligaments in sheep.

Control experiments have also been performed using sheep in which the tendo calcaneus was excised and replaced with nylon, and sheep in which no tendon substitute was used after excision.

Experiments

In nine adult sheep the tendo calcaneus was excised from its musculo-tendinous junction to the calcaneal insertion and replaced with a double plaited strand of filamentous carbon fibre previously washed in methylethyl ketone. This step is necessary to remove all traces of size applied during the extrusion process; it leaves filaments of pure carbon. It is possible to sterilise the carbon by any of the conventional methods, and in the experiments described the standard steam pressure technique was used. The

FIG. 1
Sheep: tendo calcaneus excised and replaced with a double strand of plaited filamentous carbon fibre.

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carbon was passed through the musculo-tendinous junction 2·5 centimetres above the proximal cut, and was held in place with three stout silk sutures. The distal ends were passed through a hole in the calcaneus and tied upon themselves (Fig. 1).

extension there was gross varus instability. Carbon fibre was passed through the femur from the medial to the lateral side and then led across the joint to the lateral aspect of the tibia, where it was passed through bone to the other side and anchored. This restored normal stability with full movement of the knee. The limb was not immobilised.

FIG. 2
Sheep: one month after operation. The integrity of the operated side (left) can clearly be seen.

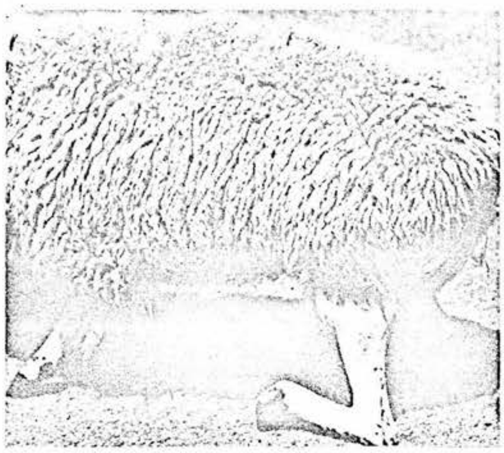

FIG. 3
Control sheep unable to bear weight on the operated side (left) in which the tendo calcaneus has been excised.

FIG. 4
The appearance of the new tendon in the sheep one year after the implantation of filamentous carbon. The new tendon is of a similar length to that on the normal side and is slightly thicker. Carbon left; normal right.

In three other sheep the tendo calcaneus was excised in a similar manner but was not replaced, and in two others a triple monofilament nylon replacement was used. In no case was the limb immobilised; all the animals were encouraged to walk as soon as possible.

In four sheep the lateral ligaments of the knee were excised in such a manner that with the knee in full

In twenty rabbits the tendo calcaneus was excised and replaced in the manner described for the sheep. The filamentous carbon was not plaited but was threaded through musculo-tendinous junction and bone as a pair of strands of unwoven fibre.

RESULTS

In one of the nine sheep in which the tendon was replaced with plaited carbon the operation site became infected. This animal was killed three weeks after operation. The other eight bore full weight on all legs at four days and all were walking at one month with little sign of an abnormal gait. At two months all these animals walked normally and it was not possible to tell which side had been operated on (Fig. 2). Five were later killed but the remaining four were still walking normally at eighteen months.

None of the animals whose tendons had been excised and not replaced bore weight on the leg operated on, and at six weeks all were walking three-legged (Fig. 3). All were killed at this stage.

The two sheep in which triple nylon strands were used to replace the tendon were unable to bear weight on the affected leg and were still walking three-legged at six weeks. The nylon was easily palpable beneath the skin and in one it was possible to feel a gap between muscle and nylon.

The four sheep in which the lateral ligaments of the knee were replaced with plaited carbon all stood normally within a week, and all were walking normally at one month. All have survived at least nine months with no sign of lateral ligament instability and demonstrate a full range of knee movement.

In the dissected specimens from sheep with carbon substitutes there was a strong whitish cord of fibrous tissue around the implant. The carbon implant was still visible at four to six weeks, but by three months it had become buried in tendon-like tissue. At one year the only difference apparent to the naked eye between the operated and the normal side was that the tendon operated upon was slightly thicker (Fig. 4).

On histological examination most of the carbon filaments originally closely grouped together were found to be widely separated by masses of newly formed fibrous connective tissue which exceeded the volume of the originally implanted carbon ribbon by six to twelve times.

At eight weeks the new tendon had a similar appearance to that on the normal side but it was of a slightly greater diameter and this slight increase in size was maintained at one year.

Although small groups and individual filaments of carbon were accompanied by a mild granulation tissue histiocyte reaction, the dense fibrous connective tissue

FIG. 5

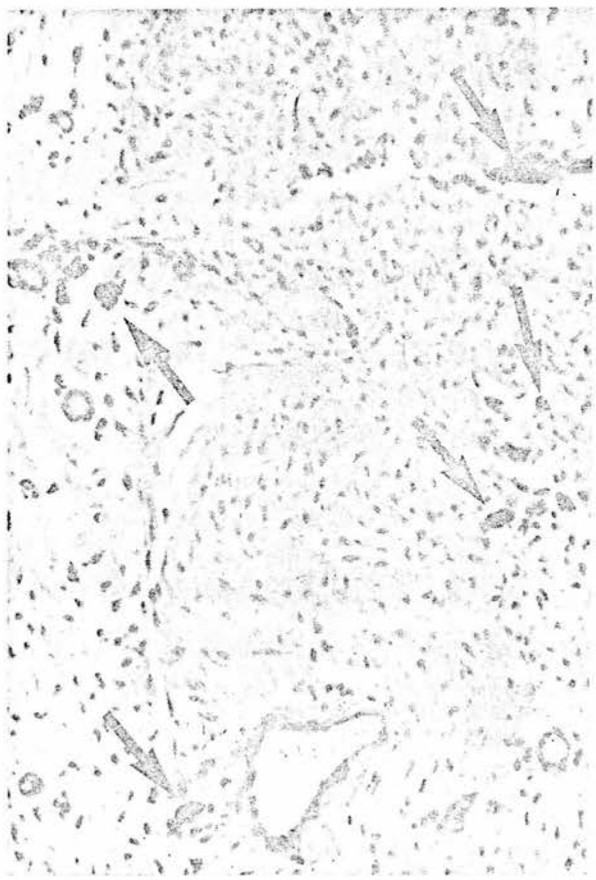

FIG. 6

Figure 5—Filamentous carbon implant replacing the calcaneal tendon. Although there is a mild foreign body histiocyte reaction, the individual carbon filaments (arrowed) are spread apart by masses of newly formed fibrous connective tissue, the cells and fibres of which resemble the structure of normal tendon. (Haematoxylin and eosin, ×125 approximately.) Figure 6—New tendon eight weeks after carbon implantation. The individual carbon filaments (arrowed) are widely separated by masses of dense fibrous tissue organised in bundles like normal tendon. (Haematoxylin and eosin, ×85 approximately.)

did not show any signs of inflammatory or foreign body reaction (Fig. 5). With continuing normal function the elements became more differentiated and became organised along the lines of stress, thus gradually coming to resemble normal tendon structure (Fig. 6).

In the sheep in which the tendo calcaneus had been replaced with nylon there was a thin band of scar tissue with low mechanical strength. An expressed macrophage—foreign body giant-cell reaction was seen and in comparison with the filamentous carbon group there was a much less dense production of collagenous tissue.

A similarly poorly developed band was also seen in those sheep in which the tendo calcaneus had not been replaced. In all five sheep in the control group the thin scar tissue band totally failed to support the calcaneus and resulted in the collapse seen in Figure 3. The appearance of the band was in marked contrast with that of the well developed tendon of the correct length seen in the carbon group.

As in the sheep, a strong tendon-like whitish cord developed around the implanted carbon ribbon in the rabbits. In some specimens only the distal part of the carbon implant was visible during dissection after eight to twelve weeks.

The rabbit implants were tested for breaking strain and compared with previously established normal levels. Initially the implant broke away from the musculotendinous junction at 2·00 kilograms but the strength rose gradually to normal breaking strain at eight weeks. Thereafter the new tendon broke in a variety of different places and within normal limits (Fig. 7).

Microscopically the picture was identical to that seen in the sheep. There was massive production of functioning dense connective tissue which, after eight to twelve weeks, became organised into bundles along the direction of pull in the same way as normal tendon tissue.

In some specimens at twelve weeks it was apparent that the rabbit implants had undergone partial disintegration, but in all the same pattern of connective tissue organisation was seen irrespective of the presence or absence of partial carbon disintegration.

DISCUSSION

The potential biological and biomechanical significance of pure carbon was suggested by Benson (1971) and it has recently become possible to manufacture carbon in a number of forms which lend themselves to use as implants.

Our experiments with filamentous carbon suggest that it is accepted in living tissues with virtually no adverse reaction. It appears that the filamentous implants have the power of attracting connective tissue ingrowth within their interstices with the laying down of substantial deposits of strong collagenous fibres. When placed in a functional position and subjected to forces predominantly in one direction, these collagen fibres appear to have gradually orientated themselves in one direction so that, after eight to twelve weeks, a structure very closely resembling a natural tendon or ligament results. In the unplaited form it appears that the original carbon fibre may disintegrate having outlived its useful period and has thus acted as a temporary scaffold into which new tissue can grow. The rapid development of new collagenous tissue suggests that this has been induced, in part at least, by the presence of the carbon.

One may speculate that the key to success is the gradual mechanical failure of the carbon that allows a gradually increasing load to fall on the newly forming collagen and so encourages the fibroblasts to become orientated in the direction of stress.

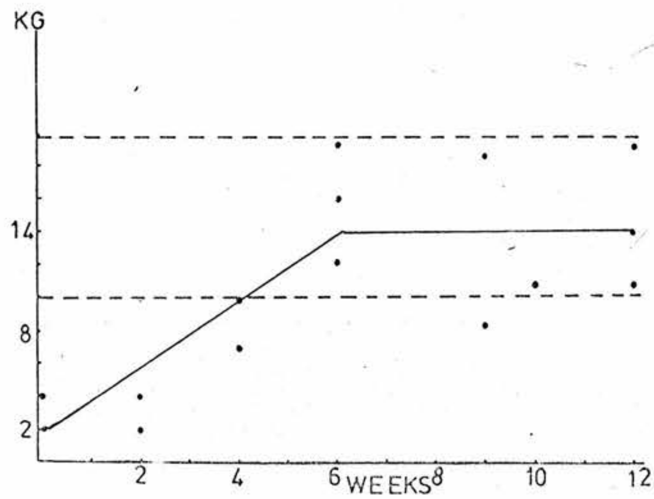

FIG. 7

Graph showing the breaking strains of the carbon-induced tendo calcaneus in the rabbit. The normal range of breaking strains in ten rabbits of similar age is shown between the dotted lines (10–20 kilograms).

It certainly appears that filamentous carbon can be used to induce the formation of new tendon or ligament with a physical strength equal to that of the normal structure. This phenomenon has obvious clinical significance. Clearly, since the formation of the new structure is dependent on the extensive invasion of connective tissue its use as a ligament is restricted to those sites where adhesion formation is of little consequence.

Trevor (1950) drew attention to the fact that a thin band of tissue grew along the line of the original tendon when the divided ends of a tendon were not approximated. In our control animals in which the tendon was not replaced a similarly poorly developed band was seen. Trevor's use of nylon as a bridging material encouraged us to use this material in our second control group and we also found a thin poorly developed band of tissue along the line of the nylon. The effect of the carbon implants was different in three respects. Firstly, a new tendon of size and strength similar to that of the normal side developed. Secondly, no sinuses formed, and thirdly, the histological evidence suggested that the new tendon was actually induced to form by the presence of the carbon.

It is in this last respect that filamentous carbon differs fundamentally from all other forms of tendon replacement materials. Although some success has been achieved using materials such as silk (Henze and Mayer 1914), Teflon (Williams 1960), Silastic (Bader and Curtin 1968) and Silastic with Dacron (Salisbury, Mason, Levine, Pruit and Wade 1974), all of these have been used simply to replace tendons. Filamentous carbon is only similar to these materials in the first weeks after implantation. Thereafter the newly induced tendon takes over the action of the implant and the implant itself becomes progressively more irrelevant to normal function. The partial disintegration observed in some animals indicates that the implant has outlived its usefulness and has truly acted as a temporary scaffold while new tendon develops. Thus there is no need to consider the time over which such an implant will last before mechanical failure occurs.

We have demonstrated two possible uses: for rupture of the tendo calcaneus when the diagnosis is made long after injury and when there is a large gap; and for the repair of collateral ligaments. It remains to be seen, however, whether the early promise in rabbits and sheep is borne out by experience in man. The similar response in man and sheep to nylon implantation encourages us to believe that the human response to filamentous carbon fibre implantation will be no different from that observed in the sheep.

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